UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00480
Patent 7,713,947

Case IPR2023-00481
Patent 8,377,903

DECLARATION OF DR. BERND MEIBOHM

Merck 2052
Hopewell v Merck
IPR2023-00480

I, Dr. rer. nat. Bernd Meibohm, declare as follows:

I. INTRODUCTION

1. I have been asked by counsel for Merck Serono S.A. ("Patent Owner") to provide my opinion in connection with the following *Inter Partes* Review proceedings: IPR2023-00480 ("'480 IPR") and IPR2023-00481 ("'481 IPR"). I understand that the subject of the '480 IPR is U.S. Patent No. 7,713,947 ("the '947 patent") and the subject of '481 IPR is U.S. Patent No. 8,377,903 ("the '903 patent").

2. I am providing this declaration as an expert in pharmaceutics and clinical pharmacology.

3. In forming my opinions set forth in this Declaration, I have considered and relied on my education and experience in the field of pharmaceutical science, including pharmacokinetics, pharmacodynamics, clinical trial design, and pharmaceutical drug development. In preparing this Declaration, I have also reviewed and considered the documents identified in Appendix B.

4. This Declaration identifies my opinions to date. I reserve the right to amend or supplement this Declaration, if allowed under the relevant rules, to address any issues raised by Petitioner, Petitioner's expert(s) or resulting from further discovery relating to any of the opinions stated herein.

II. BACKGROUND AND QUALIFICATIONS

5. I am currently a Distinguished Professor, Associate Dean for Research and Graduate Programs, and Chair of the Department of Pharmaceutical Sciences at the College of Pharmacy, The University of Tennessee Health Science Center located in Memphis, Tennessee.

6. A detailed recitation of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is attached as Appendix A to this Declaration. A brief discussion of my experience and qualifications is included below.

7. I trained as a pharmacist at the Technical University Carolo-Wilhelmina in Braunschweig, Germany from 1984 to 1988. From 1988 to 1989, I completed practical training as a pharmacist in Germany. From September 1989 to July 1994, I completed my doctoral degree (Dr. rer. nat., *i.e.* Doctor of Natural Sciences) in Pharmaceutics at the Technical University Carolo-Wilhelmina.

8. After receiving my board certification in clinical pharmacy from the Pharmacist Guild of Lower Saxony in 1992, I undertook a postdoctoral research fellowship in Clinical Pharmacology at the University of Florida from November 1995 to October 1997.

9. From November 1997 to December 1998, I was a Visiting Assistant Professor of Pharmaceutics in the Department of Basic Pharmaceutical Sciences at

the College of Pharmacy, the University of South Carolina, and from January 1999 to July 1999 I was an Assistant Professor of Pharmaceutics at the University of South Carolina.

10. In 1999, I joined the University of Tennessee. From August 1999 to June 2002, I was an Assistant Professor of Pharmaceutical Sciences in the Department of Pharmaceutical Sciences at the College of Pharmacy. From July 2002 to June 2007, I was an Associate Professor and in 2007, I became a tenured member of the faculty. From July 2007 to the present, I have been a Professor of Pharmaceutical Sciences at the University of Tennessee Health Science Center. In 2021, I became a UTHSC Distinguished Professor. I also hold the Harriet S. Van Fleet Endowed Professorship in Pharmaceutics, and I serve as Chair of the Department of Pharmaceutical Sciences at the University of Tennessee Health Science Center.

11. In addition to my Professorship, I have been the Associate Dean for Research and Graduate Programs for the College of Pharmacy at the University of Tennessee Health Science Center since 2008.

12. In the course of my career, my research focus has primarily been on pharmacokinetic and pharmacodynamic principles for pre-clinical and clinical drug development and applied pharmacotherapy. My focus has been on small molecule drugs.

13. I have also worked with biologic drugs (also referred to as 'biologics'), which include therapeutic proteins derived from living cells and organisms.

14. Additionally, I have worked on the development of various anti-infective drugs and anti-viral drugs. Specifically, my research has included profiling pharmacodynamic and pharmacokinetic properties of novel chemical entities, to identify which compounds have the potential for therapeutic use and how they can best be used to achieve maximum efficacy and minimal toxicity. This includes the exploration of different routes of administration (including oral, intravenous, subcutaneous, and pulmonary drug delivery) as well as different dosing regimens for approved and new drug candidates. Part of my research has included working on developing dosing regimens for drugs in different patient subgroups.

15. Throughout my career, I have been a member of and served the American Association of Pharmaceutical Scientists, the American College of Clinical Pharmacology, and the International Society of Pharmacometrics. I have published more than 200 books, book chapters and peer-reviewed scientific journal articles.

16. In addition to my above qualifications and experiences, I have served as a consultant to drug manufacturers in pre-clinical and clinical capacities. In the

past, I have consulted for and been invited to present my research by Merck KGaA on various pharmacokinetic and pharmacodynamic issues. My last such work with Merck was in 2022. My prior experience with Merck KGaA has no bearing or effect on my opinion as provided in this declaration.

17. Over the course of my career, I have also interacted with various experts and inventors in pharmaceutics, including Dr. Nicholas Bodor, who I understand to be a named inventor of the PCT Application WO 2004/087101 (the "Bodor" reference or "Bodor"). '480 Ex. 1022; '481 Ex. 1022. My prior interactions with Dr. Bodor has no bearing or effect on my opinion as provided in this declaration.

18. I am being compensated for my time in connection with this IPR at my standard legal consulting rate, which is $600/hour. My compensation is in no way contingent on the substance of my testimony or the outcome of this or any other proceeding. I have no interest in this proceeding.

III. SUMMARY OF OPINIONS

19. I understand that the Petitions allege that claims 36, 38, 39, 41-46 of the '947 patent, and claims 17, 19, 20, 22-27 of the '903 patent are obvious in view of Bodor and Stelmasiak. '480 Pet. 8-9; '481 Pet. 8-9. It is my opinion that a POSA, as advised by a pharmacologist, would not be motivated to combine or modify Bodor and Stelmasiak.

20. ***First***, Bodor and Stelmasiak fail to teach or suggest weight-based dosing of cladribine and a POSA, advised by a pharmacologist, would not have been motivated to modify Bodor and Stelmasiak's flat, fixed dosing regimens to a weight-based dosing regimen, or have had any reasonable expectation of success in doing so. As I will discuss further below, weight-based dosing and flat, fixed dosing are fundamentally different. Neither Bodor nor Stelmasiak teaches or suggests weight-based dosing; they only teach the use of a flat, fixed dose for their disclosed formulations, which a POSA, advised by a pharmacologist, would not have been motivated to convert to a weight-based dosing regimen in view of Bodor or Stelmasiak's teachings.

21. ***Second***, a POSA, with the advice of a pharmacologist, would not have been motivated to combine/modify Bodor and Stelmasiak at least because Bodor teaches a formulation having lower bioavailability compared to Stelmasiak's formulation. And whereas Bodor teaches no multiple sclerosis ("MS") treatment efficacy and Stelmasiak reported only limited MS treatment efficacy, a POSA would not have been motivated to lower the dosage in Stelmasiak's regimen to the dosage disclosed in Bodor, or have had any reasonable expectation of success in doing so. Specifically, because a POSA would have understood the foregoing, a POSA would not have been motivated to modify Stelmasiak's initial treatment

phase of 300 mg administered orally over six months with Bodor's 100-140 mg cladribine doses administered orally over two months.

22. ***Lastly***, it is also my opinion that Petitioner's Declarant, Dr. Miller, fails to support his argument that a POSA would have been motivated to combine or modify Bodor and Stelmasiak to arrive at the claimed dosing regimen.

IV. PERSON OF ORDINARY SKILL IN THE ART

23. Petitioner asserts that "[a] POSA for the ['903/'947 patents] would have the knowledge of multiple disciplines, such as immunology, biochemistry, and human physiology and anatomy, and also typically be a clinician with experience and/or training in neurology." '480 Pet. 28; '481 Pet. 28. Petitioner further asserts that a "POSA typically would be a medical doctor with a specialty in neurology, specifically in treating autoimmune disorders of the nervous system, such as multiple sclerosis, and typically at least 2 years of experience with administering treatments to patients and evaluating results of such treatments, as well as experience or knowledge in related research and development." '480 Pet. 29; '481 Pet. 29. According to Petitioner, a POSA "would have drawn upon the knowledge and experience of related disciplines of a multi-disciplinary team that might lie outside the POSA's primary training" such as "the knowledge and experience of a pharmacologist on a multi-disciplinary team to determine the appropriate dose for a particular patient." '480 Pet. at 28; '481 Pet. at 28.

24. It is my opinion that a pharmacologist on any such multi-disciplinary team would have had specific experience investigating and comparing the pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, developing pharmaceutical drugs and designing clinical trials.

25. In my opinion, a POSA with respect to the inventions described in the challenged claims is a person having an M.D. with at least two years of experience treating neurological conditions, with a focus on autoimmune disorders, including but not limited to multiple sclerosis, and prescribing immunotherapies to treat such neurological conditions. A POSA would also be part of a team including individuals with experience in investigation of the pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, pharmaceutical drug development, and clinical trial design.

26. Under either definition, a POSA would have access to or rely on the knowledge and expertise of a pharmacologist, including knowledge and expertise in investigating and comparing the pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, which include studies of drug dosing routes and bioavailability. I have been an expert in pharmacology including pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, pharmaceutical drug development, and clinical trial design since well before 2004. Thus, my background, expertise, and knowledge with respect to pharmacology would be a part of the knowledge and

expertise a POSA would draw upon or rely on under either definition of a POSA. I am providing my opinion from the perspective of a pharmacologist who would advise a POSA and what a POSA would understand in consultation with a pharmacologist. My opinion is the same under either party's definition of a POSA.

V. TECHNICAL BACKGROUND

A. Pharmacokinetics

27. Pharmacokinetics ("PK") is the study of a drug's absorption, distribution, metabolism, and excretion when administered to a patient's body, in other words, the relationship between drug administration and the resulting levels of that drug in the body.

28. A drug's PK properties may depend on many factors including dosage form, route of administration, and individual properties of the drug and the treated patient.

29. Bioavailability refers to the percentage of an administered dose of a drug that reaches the systemic circulation in the treated patient. Bioavailability of a drug may vary among patients and patient populations.

30. A standard method for determining the bioavailability of a drug is to use the area under the concentration-time curve ("AUC"). AUC is a measurement of the extent of absorption of the drug, i.e., it is a measure of a patient's cumulative systemic exposure to the drug from administration through complete clearance of the drug. AUC is calculated by plotting the concentrations of the drug in the body

(e.g., in plasma) versus different time points to construct a curve and measuring the area under the curve.

31. In general, a drug's PK properties are affected by the method or route of administration. For example, an intravenously administered drug is injected directly into a patient's vein to directly reach systemic circulation. Thus, for intravenous ("IV") drugs, the bioavailability of a drug is generally 100%. Subcutaneously administered drugs are injected in a site under the skin into tissue. Unlike IV administration, the drug must be absorbed into the systemic circulation from the subcutaneous injection site. Bioavailability of subcutaneous (SC) drugs is typically, but not always, lower than IV. Last, for orally administered drugs, the bioavailability is commonly lower than for IV administration and often also lower than for the SC administered route of the same drug. This is because the orally administered drugs will need to first be absorbed through the gastrointestinal system and then pass through the liver, which typically metabolizes at least a portion of the drug, before the remaining drug can enter the systemic circulation.

32. Bioavailability of orally-administered drugs (e.g., tablets or oral solutions) can be determined by calculating the AUC from a drug concentration-time point curve. Specifically, blood from treated patients can be taken at periodic intervals after drug administration to determine the drug concentrations to plot a curve and the AUC can be calculated from such a curve. Bioavailability is

typically calculated by comparing the AUCs of a drug orally-administered vs. intravenously administrated. Ex. 2043, 1515.[1]

33. PK properties of a drug usually influence the design of an appropriate dosing regimen. PK properties may inform how to select a drug's optimal dose, dosing method or dosing schedule. When designing a dosing regimen, one important consideration is a drug's overall bioavailability, because it informs the percentage of the administered drug that actually reaches the systemic circulation in the treated patient. Ex. 2063, 3.

34. Among a patient population, patients will have different weights. Depending on the drug and its formulation, patient weights may affect drug concentrations in the patients' blood and whether an administered dose of a drug is therapeutically adequate or toxic, even when the same absolute amount of a drug is given. In some instances, the same amount of a drug, e.g., 100 mg, may well be sufficient for a patient with lighter weight to result in acceptable pharmacologic effect, but may fail to result in sufficient therapeutic effects in a heavier patient as an increase in body size and weight may mean a larger volume of distribution and a higher drug-clearance from the body. For instance, low molecular weight

[1] All citations to Patent Owner's exhibits are in reference to Patent Owner's exhibit filed contemporaneously in IPR2023-00480 and IPR2023-00481.

heparins such as tinzaparin need to be dosed based on body weight. *See* Ex. 2062, 817. For some drugs, however, the variability in pharmacologic effect by weight may be minimal. In these cases, a fixed or flat dosing of a drug would be the preferred dosing method for better compliance and easy administration.

35. A drug treatment dosage can be designed using a number of dosing approaches. The most common dosing regimens are flat, fixed dosing. A flat, fixed dosing regimen is a regimen in which a drug is administered without consideration of a patient's weight. In contrast, in a weight-based dosing regimen (also known as bodyweight-based), each patient will get a different dose of a drug that is proportional to that patient's body weight.

36. I understand that by 2004, there were several drugs approved by the FDA for treating MS. Among these, the interferons Betaseron®, Avonex®, and Rebif® are administered 0.25 mg every other day, 30 µg/week, and 44 µg three times/week, respectively; Tysabri® (natalizumab) is dosed 300 mg once every four weeks; and Copaxone® (glatiramer acetate) is administered 20 mg/day. Ex. 2014 (Betaseron_Label), 12; Ex. 2015 (Avonex_Label), 3; Ex. 2016 (Rebif_Label), 17; Ex. 2019 (Tysabri_Label), 10; Ex. 2017 (Copaxone_Label), 19. All of these MS drugs are administered using a flat or fixed dose.

37. On the other hand, Mavenclad® is dosed by weight. Ex. 2001 (Mavenclad® Label), 1. As described in "2.2 Recommended Dosage," "[t]he

recommended cumulative dosage of MAVENCLAD is 3.5 mg per kg body weight administered orally and divided into 2 treatment courses (1.75 mg per kg per treatment course). . . ." Ex. 2001, 5. As previously noted, weight-based dosing may be better in achieving the same pharmacological effect across patients with different body weights. *See* Ex. 2062, 822-23.

B. The '947 and '903 Patents

38. I have reviewed both the '947 and '903 patents that are the subject of the above referenced *inter partes* review proceedings. The '947 and '903 patents recite claims directed to methods of treating certain forms of multiple sclerosis using a four-step weight-based oral administration dosing regimen. The claims recite an induction period wherein cladribine is administered using a weight-based dosage (mg/kg), a cladribine-free period, a maintenance period, and an additional cladribine-free period. '480 Ex. 1001 ('947 Patent), 19:13-30; '481 Ex. 1001 ('903 Patent), 18:7-26.

C. References

1. Bodor

39. Bodor discloses a solid oral (tablet) cladribine formulation comprising a particular cladribine-cyclodextrin complex. '480 Ex. 1022; '481 Ex. 1022. Bodor describes an oral cladribine tablet comprising a complex of inclusion and non-inclusion complexes of cladribine and cyclodextrin, which it refers to as a

"complex cladribine-cyclodextrin complex". ’480 Ex. 1022, 16:25-28; ’481 Ex. 1022, 16:25-28.

40. Bodor’s claimed cladribine-cyclodextrin formulation purports to provide “novel therapeutic modalities for the treatment of patients in need of treatment with cladribine.” ’480 Ex. 1022, 22:4-6; ’481 Ex. 1022, 22:4-6. Bodor reflects that some pharmacokinetic testing was performed with examples of the claimed formulation, including the results of that testing, but Bodor does not describe any testing for or results related to the efficacy of its claimed cladribine-cyclodextrin formulation. *Id.* In particular, Bodor discloses in “Example 3” that 3 mg (Batch N0120) and 10 mg (Batch N0126) oral cladribine tablets were manufactured for use in a clinical pharmacokinetic study. ’480 Ex. 1022, 32:5-6; ’481 Ex. 1022, 32:5-6. Bodor’s 3 mg and 10 mg oral tablets were dosed in a flat, fixed dosage in a clinical pharmacokinetic study to investigate the bioavailability of the disclosed cladribine-cyclodextrin formulations. *See* ’480 Ex. 1022, 33:25-27 at Example 4 (“Patients received randomly three different *fixed* oral doses (3.0 mg) and a *fixed* subcutaneous dose of 3.0 mg); ’480 Ex. 1022, 36:18-20 at Example 5 (“Patients received randomly two different *fixed* oral doses (3.0 mg and 10.0 mg) and a *fixed* intravenous dose of 3.0 mg[.]”) (emphases added); ’481 Ex. 1022, 33:25-27 (Example 4); ’481 Ex. 1022, 36:18-20 (Example 5).

41. With respect to "Example 4," Bodor states "[t]he objective of this study was to assess the relative bioavailability of three oral cladribine formulations" including "a cyclodextrin-based formulation according to the instant invention (Tablet 1: complex FD05, i.e. Batch No. N0120 tablets described above)," a mucoadhesive formulation, a hard-gel capsule formulation, in comparison with a fixed subcutaneous cladribine administration. '480 Ex. 1022, 33:12-23; '481 Ex. 1022, 33:12-23. Bodor's relative bioavailability study was an open-label, randomized, 4-way crossover single dose study using 12 patients with MS. '480 Ex. 1022, 33:24-25; '481 Ex. 1022, 33:24-25. In the study, patients received "three different *fixed* oral doses (3.0 mg) and a *fixed* subcutaneous dose of 3.0 mg." '480 Ex. 1022, 33:26-27; '481 Ex. 1022, 33:26-27 (emphases added).

42. Bodor explains that the plasma concentrations of cladribine were measured and plotted over various time points to determine the AUC. Bodor reported the results of its study in the table below.

TABLE VI

Ratios of Oral to Subcutaneous Pharmacokinetic Parameters and Corresponding Two-Sided 90% Confidence Intervals for Cladribine Study (n=12).

Pharmacokinetic Parameter	3 mg Tablet 1		3mg Tablet 2		3mg Capsule	
	Ratio*	LL, UL	Ratio*	LL, UL	Ratio*	LL, UL
AUC_{Inf}	43.1	35.7, 52.1	38.4	31.8, 46.4	38.9	32.1, 47.0
AUC_t	41.9	34.6, 50.8	37.2	30.7, 45.0	37.6	31.0, 45.5

*Ratios (dose normalized) and Corresponding 95% LL obtained via inverse transformation of log-transformed data.

43. Specifically, with respect to the 3 mg oral cladribine-cyclodextrin complex formulation, Bodor finds a relative bioavailability of 41.9 % and 43.1 % for its oral tablet relative to a fixed subcutaneous dose, dependent on which AUC term is used.

44. With respect to "Example 5," titled "CLINICAL STUDY: DOSE RESPONSE AND ABSOLUTE BIOAVAILABILITY," Bodor states "[t]he objective of this study was to assess the systemic availability of cladribine after oral administration in two different *fixed* oral doses, in comparison with one *fixed* intravenous administration (reference formulation) in patients with MS (multiple sclerosis), and to evaluate the safety and tolerability of cladribine in this population." '480 Ex. 1022, 36:12-16; '481 Ex. 1022, 36:12-16. Bodor's absolute bioavailability study was an open-label, randomized, 3-way crossover single dose

study consisting of twenty-six patients with MS. In the study, patients purportedly "received two different fixed oral doses (3.0 mg and 10.0 mg) and a fixed intravenous dose of 3.0 mg . . . ." '480 Ex. 1022, 36:17-20; '481 Ex. 1022, 36:17-20.

45. In the clinical study disclosed in "Example 5," Bodor determined the area under curve ("AUC") by plotting the concentrations of cladribine in patient plasma over various time points. Bodor reported the results of its study in the table below.

TABLE VIII

Ratios of Oral to I.V. Pharmacokinetic Parameters and Corresponding Lower Limit (LL) for the one-sided 95% Confidence Interval for Cladribine Study (n=26)

Pharmacokinetic Parameter	Oral Administration			
	3.0 mg		10.0 mg	
	Ratio*	LL	Ratio*	LL
AUC_{inf}	34.5	31.7	39.1	35.9
AUC_t	34.0	31.2	39.4	36.1

*Ratios (dose normalized) and Corresponding 95% LL obtained via inverse transformation of log-transformed data.

46. Specifically, with respect to the 10 mg oral cladribine-cyclodextrin complex formulation, Bodor found an absolute bioavailability of 39.1 and 39.4% for its 10 mg oral tablet, in comparing against the AUC obtained by using an intravenously-administered cladribine dosing route. Indeed, Dr. Miller confirms

that "the bioavailability that Bodor reports for its 10 milligram tablets is 39.1 or 39.4 percent[.]" Ex. 2009, 61:13-18.

47. With respect to the bioavailability studies conducted using Bodor's claimed cladribine-cyclodextrin formulations, a POSA would have understood that Bodor reported a relative bioavailability of 41.9 % and 43.1% for its 3 mg tablet compared to subcutaneous administration, and an absolute bioavailability of 39.1 and 39.4% for its 10 mg oral cladribine-cyclodextrin tablets. '480 Ex. 1022, 36 (Table VI); '480 Ex. 1022, 38 (Table VIII); '481 Ex. 1022, 36 (Table VI); '481 Ex. 1022, 38 (Table VIII). In Bodor's disclosed clinical bioavailability studies discussed in "Examples 4 and 5," all of the doses of oral, subcutaneous, and intravenous administrations were flat, fixed doses, not weight-based doses.

48. Bodor does not disclose any MS efficacy studies using its cladribine-cyclodextrin oral tablets. Bodor also does not describe a treatment regimen for any proposed clinical study. Bodor, does, however, discuss a theoretical treatment regimen:

> At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment.

'480 Ex. 1022, 23:15-20; '481 Ex. 1022, 23:15-20.

49. The above proposed treatment regimen expressly discloses only a flat dose of 10 mg/day for five to seven days for a two-month period, followed by 10 months of no treatment. The disclosure of the theoretical treatment regimen indicates that patients may receive a cumulative oral dose between 100 mg and 140 mg (inclusive). The disclosure does not reference patient weight at all or provide any criteria from which to determine whether or how different doses would be given to different patients. As would be expected with flat, fixed dosing, the above theoretical regimen is administered without consideration of patient weight. Thus, Bodor's disclosed treatment regimen does not disclose any weight-based dose or associate any dose with any patient (by weight or otherwise).

2. Stelmasiak

50. Stelmasiak is a report of a cladribine study published in 1998 (the "Stelmasiak study"). '480 Ex. 1013, 4; '481 Ex. 1013, 4. The Stelmasiak study involved 10 patients with remitting-relapsing MS, who were treated with either a 10 mg cladribine saline liquid solution administered orally or a 5 mg cladribine saline liquid solution administered subcutaneously, once daily for five consecutive days (50 mg oral dose; 25 mg SC dose). This treatment course was given once a month for 6 months followed by additional 1- month courses (again using 50 mg oral dose or 25 mg SC dose) at month 9 and month 12 or 15. '480 Ex. 1013, 5; '481 Ex. 1013, 5. As described in the above treatment regimen from Stelmasiak,

patients received a 300 mg cumulative flat oral cladribine dose over the first 6 months of treatment followed by 50 mg at month 9, and 50 mg at either month 12 or month 15. ’480 Ex. 1013, 5; ’481 Ex. 1013, 5.

51. With respect to the 10 mg cladribine oral solution, Stelmasiak utilized a formulation prepared as a phosphate-buffered solution. As described in Stelmasiak, the oral formulation was “a sterile solution in isotonic saline” and “phosphate-buffered at pH 7.4.” ’480 Ex. 1013, 5; ’481 Ex. 1013, 5. Both the oral solution and the subcutaneous injection were administered as flat, fixed doses. No placebo or control arm was used in the study.

52. As Stelmasiak reports, six patients received a subcutaneous cladribine dose while four patients received Stelmasiak’s oral liquid formulation. Although Stelmasiak dosed every patient using a flat, fixed dose regardless of patient weight, Stelmasiak did report on the patient weights of the study group. ’480 Ex. 1013, 5; ’481 Ex. 1013, 5. Stelmasiak’s 10-person study group consisted of 8 females and 2 males, aged 21-51 years, and between 52-75 kg (median body weight was 66 kg). ’480 Ex. 1013, 5; ’481 Ex. 1013, 5. Due to the flat, fixed dosing and the different weights of each patient, Stelmasiak was able to investigate the effect, if any, of weight on the pharmacokinetic properties of its oral liquid formulation. In that regard, Stelmasiak reports that “[t]here was no indication that a ‘good response’ is related to the actual cladribine dose per body weight” and that “there was no

correlation between the depth of lymphocyte nadir, or the magnitude of lymphocyte count reduction from the initial value, and the drug dose expressed per kg of body weight." '480 Ex. 1013, 7, 6; '481 Ex. 1013, 7, 6.

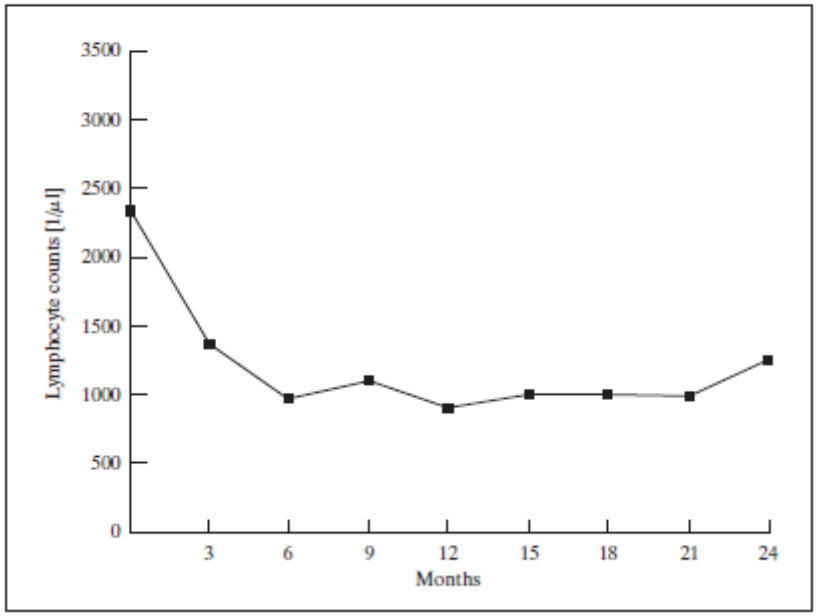
53. Stelmasiak reports some limited efficacy results as measured by EDSS scores during and after treatment, and the reduction in relapse rate. '480 Ex. 1013, 6 ("Analysis of the data for the whole group revealed that EDSS scores were significantly reduced during the treatment compared to the initial values … (Table 1)."; '480 Ex. 1013, 7 ("The relapse rate in some (but not all) patients is impressively decreased."); '481 Ex. 1013, 6; '481 Ex. 1013, 7. Stelmasiak further describes the study group as "responders" and "non-responders" based on whether there were changes in their relapse rate during the treatment period. '480 Ex. 1013, 6; '480 Ex. 1013, 7; '481 Ex. 1013, 6; '481 Ex. 1013, 7. Stelmasiak does not disclose which of the "responders" or "non-responders" received Stelmasiak's oral solution or subcutaneous injection.

54. Stelmasiak's study also reports lymphocyte count for the study group during the treatment period. As stated in Stelmasiak, "[t]he magnitude of lymphocyte count reduction varied among the patients was different in particular cases, ranging from virtually no effect in one patient to a transient drop by 80% of the initial value. … However, there was no correlation between the depth of lymphocyte nadir, or the magnitude of lymphocyte count reduction from the initial

value, and the drug dose expressed per kg of body weight … ." '480 Ex. 1013, 6; '481 Ex. 1013, 6. Although Stelmasiak plots the average lymphocyte count across the study group during and after treatment (Figure 1), Stelmasiak does not disaggregate this data by any individual patient data or study parameters. Stelmasiak does not report lymphocyte count by patients who received an oral cladribine solution or subcutaneous injection. Stelmasiak does note that of the three "non-responders" in the study, two "non-responders" "showed the reduction of approximately the same magnitude as in some of the 'responders'" with respect to lymphocyte count. '480 Ex. 1013, 6; '481 Ex. 1013, 6.

55. As shown in Figure 1 below, Stelmasiak reported a reduction in lymphocytes per microliter at 3 months (wherein the cumulative dosage of cladribine under Stelmasiak's regimen would have been 150 mg) and 6 months (wherein the cumulative dosage of cladribine under Stelmasiak's regimen would have been 300 mg) and throughout a 2-year period.

Figure 1. Average lymphocyte counts during and after treatment with cladribine.



’480 Ex. 1013, 5 (Figure 1); ’481 Ex. 1013, 5 (Figure 1).

56. In addition to the limited efficacy findings discussed above, Stelmasiak reports the bioavailability of the oral formulation used in its study, with reference to an earlier study authored by Liliemark, Albertioni, Hassan, and Juliusson, “On the bioavailability of oral and subcutaneous 2-chloro-2’-deoxyadenosine in humans: alternative routes of administration,”[2] which I will discuss in greater detail below. ’480 Ex. 1013, 5; ’481 Ex. 1013, 5.

[2] It appears the citation to Liliemark (reference No. 12 in Stelmasiak) contains a typographical error: the year of the Liliemark study’s date of publication is 1992 and not 1991. This citation error has no bearing on my opinion.

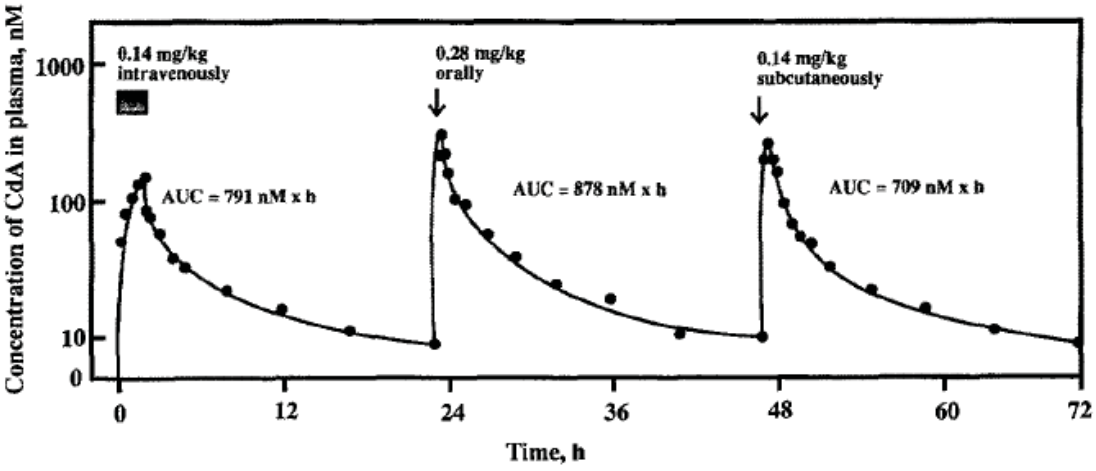
57. According to Stelmasiak, the 5 mg subcutaneous cladribine dose and the 10 mg oral cladribine dose "produce equivalent area under the concentration time curve of the drug," citing to the bioavailability data reported in Liliemark. '480 Ex. 1013, 5; '481 Ex. 1013, 5. Because Liliemark determined that subcutaneous administration of cladribine has 100% bioavailability (same as the IV administration of cladribine), and because Stelmasiak states that twice as much oral cladribine (10 mg) will result in the same AUC as 5 mg subcutaneous cladribine, Stelmasiak thus reports a bioavailability of its oral solution to be approximately 50%, which is consistent with the value reported by Liliemark. '480 Ex. 1013, 5; '481 Ex. 1013, 5; *see* '480 Ex. 2043, 1515-1516 ("[T]he bioavailability of CdA administered orally is only approximately 50%."), 1514 ("The bioavailability of SC CdA was 102% ± 28% (mean ± SD)").

58. The Liliemark bioavailability study determined the cladribine plasma concentrations in 13 patients who received either a cladribine IV infusion, subcutaneous injection, oral enteric-coated capsule, or phosphate-buffered saline solution. Ex. 2043, 1514.

59. In the Liliemark study, cladribine, (i.e. "CdA" or "2-chloro-2'-deoxyadenosine") was dissolved in a pyrogen-free phosphate-buffered saline ("PBS") solution and diluted to a concentration of 2 mg/mL for IV infusion. Ex. 2043, 1515. The 2 mg/mL PBS solution was used directly for subcutaneous

injection and administered in a 0.14 mg/kg dose. The 2 mg/mL PBS solution was also used directly for oral ingestion, administered as either 0.14 mg/kg or 0.28 mg/kg. Ex. 2043, 1515.

60. For the 2 mg/mL PBS solution, Liliemark plotted the plasma concentration of cladribine after administration of the PBS solution as an IV, subcutaneous injection, and oral ingestion. Liliemark obtained the following AUC concentrations for each administration method:



61. As Dr. Miller confirms, "Liliemark is conveying that bioavailability can be measured based on AUC values[.]" Ex. 2009 (Miller Tr.) 57:11-14.

62. Liliemark reports that the bioavailability of the PBS solution was 48% +/- 8% when administered orally at 0.14 mg/kg and 55% +/- 17% when administered orally at 0.28 mg/kg. Ex. 2043, 1515 (stating that "The bioavailability of CdA [is] 48% +/- 8% when CdA was administered orally as a PBS. When the dose of CdA administered orally was doubled, the bioavailability

was 55% +/- 17%.”). In contrast, Liliemark reports that the bioavailability of the PBS solution was 102% +/- 28% when administered subcutaneously. *Id*.

63. In particular, Liliemark states, “[w]hen administered orally at about twice the intravenous dose, the areas under the concentration time curve, AUC, are similar.” Ex. 1048, 122. Liliemark concludes that “the bioavailability of CdA administered orally is only approximately 50%, [but that] an AUC and a pharmacokinetic profile that resembles that of a 2-hour IV infusion can be obtained if the dose is doubled.” Ex. 2043, 1516. As Dr. Miller confirmed, Liliemark’s oral cladribine solution reports approximately 50% bioavailability. Ex. 2009 (Miller Tr.), 58:6-11.

64. As discussed further below, a pharmacologist would understand that Stelmasiak’s oral cladribine solution is substantially the same as the oral cladribine solution tested by Liliemark, and thus should have substantially the same bioavailability as the oral cladribine solution tested in Liliemark. Specifically, Liliemark used a “2 mg/mL” cladribine solution in “phosphate-buffered saline (PBS)” “(pH = 7.4)” saline solution. Ex. 2043, 1514-15. Stelmasiak used a “1 mg/mL” cladribine oral formulation in “a sterile solution in isotonic saline” which is “phosphate-buffered at pH 7.4.” ’480 Ex. 1013, 5; ’481 Ex. 1013, 5. Therefore, both Stelmasiak and Liliemark use the same cladribine solution in the same solvent (phosphate-buffered saline (PBS)) with identical pH (pH=7.4). Thus, a

pharmacologist would have understood that Stelmasiak's oral solution would be expected to have the same bioavailability when dosed using the same oral route as Liliemark's oral solution.

65. It is my opinion that the nominal difference in the concentration of the cladribine dosing solution, i.e., 1 mg/mL vs. 2 mg/mL, would likely not have caused any difference in the bioavailability of Stelmasiak and Liliemark's oral cladribine solutions for at least the following reasons. First, the compositions of these two solutions are otherwise identical. Second, the cladribine in both solutions has already been dissolved prior to oral administration. Accordingly, there are no solubility differences that could affect bioavailability. Third, before being absorbed by a patient's gastrointestinal system to reach systemic circulation, the cladribine administered in either the 1 or 2 mg/ml solution will be further greatly diluted by the significantly larger volumes of the gastric and intestinal fluids in a patient's body, thus rendering the difference in concentration between the two solutions even more negligible. Thus, because the Liliemark and Stelmasiak formulations use an identical dosing route (oral), ingredients (cladribine in a saline solution), buffer (PBS), and pH (7.4), a POSA, as advised by a pharmacologist, would reasonably conclude that Stelmasiak and Liliemark's formulations have the same bioavailability, i.e., 50%. Ex. 2043, 1516 ("[T]he bioavailability of CdA administered orally is only approximately 50%."). This

conclusion is also consistent with Stelmasiak's disclosure, which itself states that the 5 mg subcutaneous cladribine dose and the 10 mg oral cladribine dose, "produce equivalent area under the concentration time curve of the drug." '480 Ex. 1013, 5; '481 Ex. 1013, 5.

VI. NEITHER BODOR NOR STELMASIAK TEACHES OR SUGGESTS WEIGHT-BASED DOSING.

66. The Bodor reference teaches only flat, fixed doses of cladribine. '480 Ex. 1022, 23; '481 Ex. 1022, 23. Specifically, and as discussed above in paragraphs 48-49, the Bodor reference discloses a flat, fixed dose of 10 mg, administered for five to seven days each month for a two-month period. '480 Ex. 1022, 23:16-20; '481 Ex. 1022, 23:16-20. This teaches administering only a cumulative dose of 100 mg – to 140 mg, without consideration or adjustment based on patient weight. '480 Ex. 1022, 23; '481 Ex. 1022, 23.

67. Bodor's disclosed treatment regimen and its Examples (e.g., Examples 4-5) all use flat, fixed dosing, not weight-based dosing as claimed in the challenged claims. Bodor does not discuss a proposed dosing regimen using its cladribine formulation with a specific patient weight or any relationship to weight-based dosing. Indeed, there is no mention at all of the patient weights for any patient subject to the bioavailability studies disclosed in Examples 4 and 5 and no inherent or express disclosure of the average patient weight or any weight of an MS patient. *See supra* ¶¶41-44.

68. While Bodor describes "therapeutically effective amount[s]" or "effective amount[s]" to "denote treatments at dosages effective to achieve the therapeutic result sought" and describes "[t]herapeutically effective dosages described in the literature," nothing in Bodor suggests that this would require a weight-based dose or would teach converting a flat, fixed dose to a weight-based dose. For example, Bodor does not provide any efficacy data or clinical trial data using its cladribine formulation. *See supra* ¶¶48-49. Bodor further does not disclose or teach any patient weight—whether for its bioavailability studies or any average or other patient weight. *See supra* ¶¶41-49. Indeed, a POSA, viewing Bodor as a whole, would not understand "dosages effective to achieve the therapeutic result sought" to disclose or teach weight-based dosing when the only theoretical dosing regimen discussed in relation to its cladribine formulation and the only reported patient PK studies disclosed in Bodor's Examples 4-5 all use flat, fixed dosing.

69. A pharmacologist would not understand Bodor's discussion of a theoretical oral dosing regimen using its claimed oral formulation, "10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment," to teach a weight-based

dosing regimen. Additionally, as described above, all of Bodor's examples clearly used flat, fixed dosing. It is my opinion that a pharmacologist would have understood that despite acknowledging weight-based cladribine doses in the prior art, '480 Ex. 1022, 22-23; '481 Ex. 1022, 22-23, Bodor nonetheless specifically chose to describe a theoretical flat, fixed dosing regimen for use with its cladribine formulation.

70. Stelmasiak similarly teaches only flat, fixed doses of cladribine. As discussed above in paragraphs 50-52, Stelmasiak's study taught administering only a flat, fixed cumulative dose of 300 mg of cladribine followed by two additional flat, fixed cumulative doses of 50 mg. '480 Ex. 1013, 5; '481 Ex. 1013, 5. Stelmasiak does not describe or provide a weight-based dose.

71. Indeed, as discussed above in paragraph 52, Stelmasiak's patients consisted of individuals ranging from 52-75 kg (median body weight was 66 kg). Despite each of the subjects in Stelmasiak's study having a different weight, Stelmasiak teaches providing each of these patients the same flat, fixed dose of cladribine.

72. In fact, Stelmasiak noted that "there was no correlation between the depth of lymphocyte nadir, or the magnitude of lymphocyte count reduction from the initial value, and the drug dose expressed per kg of body weight (normalized for oral vs. subcutaneous route of administration)." *See supra* ¶54; '480 Ex. 1013,

6; ’481 Ex. 1013, 6. Indeed, a pharmacologist advising a POSA would understand that Stelmasiak suggests that weight-based dosing would not only be unnecessary but would not have any impact on the reported lymphocyte count reduction reported in its study. Thus, it is my opinion that a POSA would not have been motivated to use weight-based dosing as claimed in view of Stelmasiak.

73. Neither Bodor nor Stelmasiak teaches a weight-based dose for its oral cladribine formulations. Flat, fixed dosing and weight-based dosing are different dosing methods that cannot be used interchangeably without studying the pharmacokinetic and pharmacodynamic effects of the drug administered as both a flat, fixed dose and weight-based dose. As discussed in paragraphs 35, flat, fixed dosing results in administration of a drug without consideration or adjustment based on patient weight. Flat, fixed dosing can be used when the pharmaceutical effect does not significantly depend on weight or when it is important to ensure administration convenience or patient compliance because of, for example, the reduced risk of dose miscalculation. In contrast, in weight-based dosing, as is used with drugs like Mavenclad®, patients will get different doses of a drug proportional to weight.

74. Neither the Petition nor Dr. Miller cite any pharmacokinetic or pharmacodynamic studies to support modifying Bodor’s or Stelmasiak’s disclosed flat, fixed dosing regimens to a weight-based dosing regimen.

75. Indeed, a POSA, relying on the knowledge of a pharmacologist, would not assume that a flat, fixed dose could be calculated to a corresponding weight-based dosage with the same pharmacological effect across the patient population. For flat or fixed doses like those disclosed in Bodor and Stelmasiak, patient weight distribution would lead to vastly different oral doses in units of mg/kg. This is evidenced by the weight range of Stelmasiak's subjects (52-75 kg), who would have received an oral dosage of 4.0-5.7 mg/kg if administered the 300 mg cumulative flat dose Stelmasiak actually discloses.

76. In addition, it makes sense that the only disclosed dosing regimen in Bodor is flat, fixed. A POSA in view of Bodor would want to use the flat, fixed dosing that Bodor teaches to improve convenience of drug administration and promote better patient compliance. *Cf., e.g.*, '480 Ex. 1022, 2:9-10 ("Oral delivery of drugs is often preferred to parenteral delivery for a variety of reasons, foremost patient compliance…."); '481 Ex. 1022, 2:9-10.

77. For the foregoing reasons, a POSA would not look to a formulation that uses a flat dosing regimen to design a weight-based dosing regimen.

VII. A POSA WOULD NOT HAVE BEEN MOTIVATED TO COMBINE/MODIFY BODOR AND STELMASIAK BECAUSE OF THEIR REPORTED BIOAVAILBILITY

78. I disagree with Dr. Miller's assertion that "[a] POSA would have been motivated to treat MS by administering Bodor's oral cladribine composition

according to Stelmasiak's induction period/cladribine-free period/maintenance period/cladribine-free period framework." '480 Ex. 1002, ¶99; '481 Ex. 1002, ¶99.

79. Dr. Miller asserts that "[b]oth Bodor and Stelmasiak teach a POSA to administer cladribine during an induction period. Bodor specifically instructs administering an oral cladribine composition, which has demonstrated 'enhance[d]' oral bioavailability, for a 2-month induction period." '480 Ex. 1002, ¶99; '481 Ex. 1002, ¶99. In my opinion, Dr. Miller's reliance on Bodor is incorrect.

80. ***First***, I note that Dr. Miller does not analyze any pharmacokinetic and pharmacodynamic differences between Bodor's oral tablet formulation and Stelmasiak's oral saline formulation. A POSA, relying on a pharmacologist, would have understood that Bodor and Stelmasiak report different bioavailability results for their respective drug formulations and would not have been motivated to look to Bodor to modify Stelmasiak's dosing regimen to design an oral cladribine dosing regimen.

81. As discussed in paragraph 47, Bodor reports an absolute bioavailability of 39.1 and 39.4% for its 10 mg oral cladribine-cyclodextrin tablets. '480 Ex. 1022, 38 (Table VIII); '481 Ex. 1022, 38 (Table VIII).

82. In contrast, and as discussed in paragraphs 57, a POSA would have understood that Stelmasiak's oral PBS solution reported a cladribine formulation

with 50% bioavailability. Additionally, a POSA reviewing Stelmasiak would have understood that the bioavailability for Stelmasiak's oral PBS solution would be the same as Liliemark's oral PBS solution. Stelmasiak and Liliemark both studied a cladribine formulation prepared as a phosphate-buffered pH 7.4 saline solution. *See supra* ¶¶57-64. Although the PBS solutions in Stelmasiak and Liliemark slightly differ in concentrations (1 mg/mL as used in Stelmasiak and 2 mg/mL as used in Liliemark), a POSA, as advised by a pharmacologist, would have understood that the bioavailability of the formulation would be the same because the Stelmasiak and Liliemark formulations use the same administration route (oral), substantially the same formulations of cladribine in saline-based, phosphate-buffered solution with identical pH (7.4), and because the difference between 1 or 2 mg/ml solution will be further diminished upon administration into the gastrointestinal system. *See supra* ¶¶64-65.

83. Indeed, Dr. Miller agrees that Stelmasiak and Liliemark have the same dosage form. '480 Ex. 1002, ¶110 ("Stelmasiak discloses administering oral cladribine "prepared as [a] sterile solution in isotonic saline," which a POSA would have understood was the same dosage form disclosed by Liliemark."); '481 Ex. 1002, ¶110. Because Stelmasiak's oral, saline-based formulation is the same as the oral, saline-based formulation disclosed and tested in Liliemark, a POSA would have reasonably concluded that Stelmasiak and Liliemark report the same

50% bioavailability for their respective oral PBS solutions. *See supra* ¶¶64-65. Accordingly, a POSA would have understood that Stelmasiak's oral PBS solution and dosing method reported a higher bioavailability (50%) than Bodor's 10 mg oral cyclodextrin tablet (39.1-39.4%). So, a POSA would not have been motivated to look to combine or modify Bodor and Stelmasiak, to design an oral cladribine dosing regimen. Indeed, as described above, *supra*, paragraph 33, the overall bioavailability is an important factor in designing a dosing regimen.

84. A POSA would have also understood that Bodor proposed a lower cumulative flat, fixed dose than Stelmasiak. Specifically, a POSA would have understood that Bodor disclosed a cumulative, initial treatment dose of 100-140 mg whereas Stelmasiak disclosed 300 mg for its initial treatment dose. *Compare supra* ¶¶48-49, *with supra* ¶50.

85. It would have been apparent to a POSA that Bodor's lower bioavailability and lower cumulative dose would have resulted in lower cladribine systemic exposure in patients. Given that Bodor does not report any efficacy data, as discussed in paragraph 48, a POSA would have no reason to believe that using Bodor's reported lower bioavailability formulation and lower cumulative flat dose would have been effective or successful in treating multiple sclerosis. Indeed, a POSA reviewing Stelmasiak's study would have understood that, if anything, lowering the cladribine exposure (by either lowering the dosage or using a

formulation with a reported lower bioavailability or both as in the case of Bodor) might have reduced treatment outcomes. Stelmasiak also reports that its initial 300 mg flat, fixed dose has "good" tolerance and "[s]ide effects of the therapy are mild." '480 Ex. 1013, 5, 7; '481 Ex. 1013, 5, 7. As such, Stelmasiak did not identify a reason to reduce its dose for safety and a POSA would not have been motivated to reduce Stelmasiak's cumulative dose of 300 mg to 100-140 mg as disclosed in Bodor for an initial treatment phase.

86. ***Second***, and as discussed in paragraph 48, Bodor does not disclose any clinical trials testing the efficacy or safety of its cladribine formulation or any proposed dosing regimen. Bodor reports no efficacy or safety results at all. Thus, a POSA would not have been motivated to rely on Bodor to design a dosing regimen given that Bodor does not teach that its oral formulation and theoretical flat, fixed dosing regimen achieved clinical success in treating MS.

87. Indeed, a POSA, as advised by a pharmacologist, would have appreciated that Stelmasiak's oral PBS solution and dosing regimen did yield some partial efficacy results with respect to EDSS scores and relapse rate, as discussed in paragraph 53.

88. A POSA would have appreciated, given Stelmasiak's teachings and reported treatment results, that lowering the cumulative dosage using a formulation with a lower bioavailability would be unlikely to yield the same results as

Stelmasiak. That is, given that Bodor reports no efficacy results, teaches a lower cumulative dosage (100-140 mg) in the initial dosing phase, and reports lower oral bioavailability than Stelmasiak, it would have been reasonable for a pharmacologist to advise a POSA to expect such a dosing regimen, if anything, to have *decreased* efficacy results.

89. Accordingly, a POSA would have had no reason or motivation to reduce the dosage in Stelmasiak of 300 mg at 6 months to Bodor's 100-140 mg cumulative dose in its initial dosing phase and expect to maintain or achieve improved MS treatment efficacy. If anything, a POSA would have been motivated to further *increase* Stelmasik's initial treatment dose, to improve upon its "partial" MS treatment efficacy. *See* '480 Ex. 1013, 7; '481 Ex. 1013, 7.

90. Similarly, a POSA would recognize that Stelmasiak teaches against weight-based dosing and would not be motivated by Stelmasiak's teachings to convert Stelmasiak's fixed, flat dose to weight-based dosing. *See supra* ¶¶51, 52-54.

VIII. DR. MILLER AND THE PETITION'S ARGUMENTS REGARDING MOTIVATION TO COMBINE AND REASONABLE EXPECTATION OF SUCCESS ARE UNSUPPORTED

91. ***Finally***, I have reviewed the Petitions and Petitioner's expert's declarations, and they do not change my opinion, or address the specific issues of differing pharmacokinetic, pharmacodynamic, and efficacy data (or lack thereof)

disclosed in Bodor and Stelmasiak. Neither Dr. Miller nor the Petitioner support their arguments that a POSA would have been motivated to combine Bodor and Stelmasiak because of Bodor's allegedly "improved" pharmacokinetic results.

92. Indeed, the Petitioner and Dr. Miller merely repeat the statements recited in Bodor regarding improved bioavailability, but do not explain Bodor's bioavailability studies on their own or in comparison to Stelmasiak or other cited prior art and their reported bioavailability data. Instead, Dr. Miller only cites to the general statement in Bodor that its oral cladribine cyclodextrin tablet formulation "increase[s] or enhance[s] the oral bioavailability of cladribine" without discussing the actual pharmacokinetic clinical study results disclosed in Bodor's Examples 4 and 5. '480 Ex. 1002, ¶110; '481 Ex. 1002, ¶110.

93. Indeed, although Dr. Miller himself states that "[t]he general knowledge in the art demonstrated the 'oral bioavailability of cladribine 'varies from 37 to 51 % when the saline solution for intravenous administration is given to patients to drink,'" '480 Ex. 1002, ¶110 (internal quotations omitted); '481 Ex. 1002, ¶110, Dr. Miller still asserts that a POSA would have understood Bodor's reported 39.1-39.4% bioavailability of its 10 mg tablet "to have an increased or enhanced bioavailability compared to earlier oral solutions known in the art, such as Stelmasiak." *Id*. Dr. Miller also asserts that "Bodor states that this form of cladribine would have better oral absorption and, therefore, would have better

bioavailability [] than previously used oral preparations which were saline solutions." Ex. 2009 (Miller Tr.), 143:21-44:4. However, a POSA, as advised by a pharmacologist, would understand that "oral absorption" is just part of the bioavailability determination, and is reflected in Bodor's reported bioavailability measurement for its 10 mg cladribine tablet (about 39%). These conclusions by Dr. Miller are contradicted by Bodor, Stelmasiak, and Liliemark. *See supra* ¶¶47, 57, 60-62.

IX. CONCLUSION

94. A POSA, as advised by a pharmacologist, would not have been motivated to combine and modify the teachings of Bodor and Stelmasiak at least because 1) both Bodor and Stelmasiak teach flat, fixed dosing, which is fundamentally different from weight-based dosing; 2) Bodor teaches a cladribine formulation reporting a lower bioavailability than Stelmasiak's formulation and a POSA would not have been motivated or had a reasonable expectation of success—as taught by Bodor—to lower the dosage in Stelmasiak's regimen.

95. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

96. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willfully false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: December 21, 2023 By: _____

Dr. rer. nat. Bernd Meibohm

Appendix A

Curriculum Vitae

Bernd Meibohm, PhD, FCP, FAAPS

University of Tennessee Health Science Center
881 Madison Avenue, Suite 435
Memphis, TN 38163

CURRENT POSITION AND AFFILIATION

- UTHSC Distinguished Professor
  Associate Dean for Research and Graduate Programs
  Chair, Department of Pharmaceutical Sciences
  Harriet S. Van Fleet Professor of Pharmaceutics
  College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN

RESEARCH INTERESTS AND EXPERIENCE

- Application of pharmacometrics and pharmacokinetic/pharmacodynamics (PK/PD) concepts in drug development and applied pharmacotherapy
- Application of numerical modeling and simulation to optimize pharmacotherapy in pediatric patients
- Pharmacokinetics and pharmacokinetic-pharmacodynamic correlations of therapeutic proteins

EDUCATION

Undergraduate

- Technical University Carolo-Wilhelmina, Braunschweig, Germany, Sep 1984 – May 1988, State Examination in Pharmacy (equivalent to B.S. (Pharmacy))

Internship

- Community Pharmacy, Hildesheim, Germany, Jun 1988 – May 1989, Licensed Pharmacist

Graduate School

- Technical University Carolo-Wilhelmina, Braunschweig, Germany, Sep 1989 – Jul 1994, Doctor of Natural Sciences [Dr.rer.nat.] (equivalent to Ph.D. Pharmaceutics; Advisor: Prof. Claus Führer)

  Dissertation title: 'Investigations on the Stereoselective Pharmacokinetics of Racemic Drugs Using the Antiarrhythmic Compound Mexiletine as Example'.

Postgraduate Training

- Board Certification in Clinical Pharmacy, Pharmacist Guild of Lower Saxony, Hannover, Germany, Jan 1990 – Dec 1992
- Postdoctoral Research Fellowship in Clinical Pharmacology, University of Florida, Gainesville, FL (Mentor: Prof. Hartmut Derendorf), Nov 1995 – Oct 1997
- Course 'Advanced Methods in Pharmacokinetics/Pharmacodynamics', University of California, San Francisco, CA (Drs. M. Rowland & L.B. Sheiner), March 25 - 30, 2001
- Course 'Population PK-PD Modeling & Simulation', Metrum RG, Simsbury, CT (Dr. M. Gastonguay), April 4 - 8, 2005

- FastTrac TechVenture Entrepreneur Program, TECworks and Fedex Institute & Leadership Academy, Memphis, TN, Sept 3 – Nov 12, 2009
- University of Tennessee Leadership Institute, Gatlinburg, TN, Feb 15-20, 2015
- Diversity Certificate Program, UTHSC Office of Equity and Diversity, Sept - Nov 2020

HONORS/AWARDS

- Harriet S. Van Fleet Professor of Pharmaceutics, University of Tennessee Health Science Center, 2022
- UTHSC Distinguished Professor, University of Tennessee Health Science Center, Memphis, 2021
- ACCP Excellence in Achievement Recognition, American College of Clinical Pharmacology (ACCP), 2021
- ASCPT Member Spotlight, American Society for Clinical Pharmacology and Therapeutics, October 2019
- Honorary Regent of the American College of Clinical Pharmacology (ACCP), 2019 (for life)
- BMS Mentorship in Clinical Pharmacology Award - American College of Clinical Pharmacology (ACCP), 2017
- Outstanding Mentor Academy - University of Tennessee Health Science Center College of Graduate Health Sciences, 2014
- Fellow of the American Association of Pharmaceutical Scientists (AAPS), 2011
- Excellence in Teaching Award - University of Tennessee Health Science Center Student Government Association Executive Council, College of Pharmacy, 2008
- Excellence in Teaching Award - University of Tennessee Health Science Center Student Government Association Executive Council, College of Graduate Health Sciences 2005
- Fellow of the American College of Clinical Pharmacology (ACCP), 2002
- New Investigator Award in Pharmacokinetics, Pharmacodynamics, and Drug Metabolism, American Association of Pharmaceutical Scientists (AAPS), 2000
- Teacher of the Year Award, College of Pharmacy, University of South Carolina, 1999
- Rho Chi Pharmaceutical Honor Society, 1999
- Poster Presentation Award, 10th Annual Research Showcase, University of Florida, 1997
- Postdoctoral Research Fellowship, German Research Foundation (Deutsche Forschungsgemeinschaft DFG), 1995-1997
- Honored for Outstanding Performance as Pharmacy Student, Secretary of Education and Art of the State of Lower Saxony, Germany, 1988

MILITARY SERVICE

Medical Academy of the German Army and Field Hospital Regiment 72, Munich and Hildesheim, Germany, Captain/Pharmacist, Jan 1994 – Dec 1994

LICENSURE

Licensed Pharmacist, Pharmacist Guild of Lower Saxony, Hannover, Germany

SOCIETY MEMBERSHIPS

- American Association of Pharmaceutical Scientists AAPS (since 1995)
- American College of Clinical Pharmacology ACCP (since 1998)
- American Association of Colleges of Pharmacy AACP (since 1998)
- American Society for Clinical Pharmacology and Therapeutics ASCPT (since 2006)
- International Society of Pharmacometrics ISOP (since 2011)
- Rho Chi Pharmaceutical Honor Society (since 1999)
- German Pharmaceutical Society DPhG (since 1999)

UNIVERSITY APPOINTMENTS

- Chair, Department of Pharmaceutical Sciences and Harriet S. Van Fleet Professor of Medicinal Chemistry and Pharmaceutics, The University of Tennessee Health Science Center, Memphis, TN
  January 2022 – present
- UTHSC Distinguished Professor, The University of Tennessee Health Science Center, Memphis, TN
  August 2021 – present
- Interim Chair, Department of Pharmaceutical Sciences, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  May 2021 – December 2021
- Associate Dean for Research and Graduate Programs, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  July 2008 – present
- Professor of Pharmaceutical Sciences (with tenure)
  Department of Pharmaceutical Sciences, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  July 2007 – present
- Interim Chair, Department of Pharmaceutical Sciences, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  May 2015 – August 2017
- Member, Institute for the Study of Host-Pathogen Systems, University of Tennessee, Memphis TN
  Aug 2018 – present
- Member, Drug Discovery Center, College of Pharmacy, University of Tennessee, Memphis TN
  Jul 2017 – present
- Member, Center for Pediatric Pharmacokinetics and Therapeutics/Center for Pediatric Experimental Therapeutics, University of Tennessee, Memphis TN
  Jan 2009 – present
- Associate Member, University of Tennessee Cancer Institute, Memphis TN
  Jan 2004 – 2010

- Associate Professor of Pharmaceutical Sciences
  Department of Pharmaceutical Sciences, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  July 2002 – June 2007 (since 2005 with tenure)
- Member, College of Graduate Health Sciences
  The University of Tennessee Health Science Center, Memphis, TN
  Oct 1999 – present
- Assistant Professor of Pharmaceutical Sciences
  Department of Pharmaceutical Sciences, College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN
  Aug 1999 – June 2002
- Member of the Graduate Faculty
  The Graduate School, University of South Carolina, Columbia, SC
  Jan 1999 – Jul 1999
- Assistant Professor of Pharmaceutics
  Department of Basic Pharmaceutical Sciences, College of Pharmacy, The University of South Carolina, Columbia, SC
  Jan 1999 – Jul 1999
- Visiting Assistant Professor of Pharmaceutics
  Department of Basic Pharmaceutical Sciences, College of Pharmacy, The University of South Carolina, Columbia, SC
  Nov 1997 – Dec 1998

GOVERNMENT APPOINTMENTS

- Special Government Employee, U.S. Food and Drug Administration, 2010 – 2011 & 2014-2015

PRIVATE SECTOR APPOINTMENTS

- Vice Director – Institute for Applied Healthcare Sciences e.V., Hamburg, Germany
  Aug 2002 – Dec 2009
- Board of Directors - Metrum Research Institute, Augusta, ME
  Feb 2006 – Apr 2008
- Proprietor – Meibohm Consulting LLC, Germantown, TN, 2012 - present

PROFESSIONAL PRACTICE EXPERIENCE

- Clinical Pharmacist, Pharmacy Department, General Hospital Harburg, Hamburg, Germany, Jan 1995 – Oct 1995
- Captain/Pharmacist, Medical Academy of the German Army and Field Hospital Regiment 72, Munich and Hildesheim, Germany, Jan 1994 - Dec 1994
- Clinical Pharmacist, Albert-Schweitzer-Hospital, Northeim, Germany, Sep 1989 – Dec 1993
- Community Pharmacist (part-time), Nordstemmen, Germany, Nov 1989 – Dec 1994
- Community Pharmacist, Hildesheim, Germany, Jun 1989 – Aug 1989

TEACHING EXPERIENCE

- **University of Tennessee, College of Pharmacy**
  - PHCY 1202 – Pharmacokinetics & Dose Optimization, 4 credit hours, Department of Pharmaceutical Sciences.
    - Lecturer and Recitation Leader.

      Spring 2022: 152 professional program (Pharm.D.) students, 11 contact hrs.

      Spring 2021: 186 professional program (Pharm.D.) students, 11 contact hrs.

      Spring 2020: 192 professional program (Pharm.D.) students, 13 contact hrs.
    - Director, Lecturer and Recitation Leader.

      Spring 2019: 205 professional program (Pharm.D.) students, 36 contact hrs.

      Spring 2018: 176 professional program (Pharm.D.) students, 36 contact hrs.
  - PHSC 212 – Pharmacokinetics & Dose Optimization, 4 credit hours, Department of Pharmaceutical Sciences.
    - Director (with Dr. C.R. Yates), Lecturer and Recitation Group Leader.

      Fall 2017: 171 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2016: 198 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2015: 186 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2014: 173 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2013: 164 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2012: 158 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2011: 150 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2010: 156 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2009: 189 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2008: 203 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2007: 202 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2006: 181 professional program (Pharm.D.) students, 36 contact hrs.

      Fall 2005: 129 professional program (Pharm.D.) students, 36 contact hrs.
  - PHSC 221 - Pharmacokinetics, 3 credit hours, Department of Pharmaceutical Sciences.
    - Director (with Dr. C.R. Yates), Lecturer and Recitation Group Leader.

      Spring 2005: 125 professional program (Pharm.D.) students, 42 contact hrs.

      Spring 2004: 125 professional program (Pharm.D.) students. 42 contact hrs.

      Spring 2003: 103 professional program (Pharm.D.) students. 42 contact hrs.

      Spring 2002: 100 professional program (Pharm.D.) students. 42 contact hrs.

      Spring 2001: 101 professional program (Pharm.D.) students. 42 contact hrs.
    - Director (with Dr. J.T. Dalton), Lecturer and Recitation Group Leader

      Spring 2000 100 professional program (Pharm.D.) students. 38 contact hrs.
  - PHCY 2109 - Pharmacogenomics. Lecturer.

    Fall 2022 154 professional program (Pharm.D.) students, 2 contact hrs.

Fall 2021 192 professional program (Pharm.D.) students, 2 contact hrs.
Fall 2020 186 professional program (Pharm.D.) students, 2 contact hrs.
Fall 2019 205 professional program (Pharm.D.) students, 2 contact hrs.
Fall 2018 176 professional program (Pharm.D.) students, 2 contact hrs.

- PHSC 222 - Pharmacogenomics. Lecturer.

  Spring 2017 198 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2016 186 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2015 171 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2014 166 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2013 158 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2012 150 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2011 152 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2010 186 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2009 198 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2008 204 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2007 181 professional program (Pharm.D.) students, 3 contact hrs.
  Spring 2006 118 professional program (Pharm.D.) students, 3 contact hrs.

- PHCY 1101 – Fundamentals of Drug Action. Lecturer.

  Fall 2022 102 professional program (Pharm.D.) students, 2 contact hrs.
  Fall 2021 152 professional program (Pharm.D.) students, 2 contact hrs.
  Fall 2020 187 professional program (Pharm.D.) students, 2 contact hrs.
  Fall 2019 205 professional program (Pharm.D.) students, 2 contact hrs.
  Fall 2018 176 professional program (Pharm.D.) students, 2 contact hrs.

- PHAC 813 – Advanced Pharmacokinetics, Pharmacodynamics and Drug Development, 4 credit hours, Department of Pharmaceutical Sciences.
  - Director and Lecturer.

    Fall 2021 2 graduate program (Ph.D.) students. 32 contact hrs.
    Fall 2019 2 graduate program (Ph.D.) students. 32 contact hrs.
    Spring 2017 6 graduate program (Ph.D.) students. 32 contact hrs.
    Spring 2014 4 graduate program (Ph.D.) students. 32 contact hrs.
    Spring 2012 11 graduate program (Ph.D.) students. 32 contact hrs.
    Spring 2010 8 graduate program (Ph.D.) students. 32 contact hrs.
    Spring 2008 12 graduate program (Ph.D.) students. 32 contact hrs.
    Fall 2006 13 graduate program (Ph.D.) students. 32 contact hrs.
    Fall 2003: 10 graduate program (Ph.D.) students. 32 contact hrs.
    Fall 2001: 8 graduate program (Ph.D.) students. 32 contact hrs.
  - Director (with Dr. J.T. Dalton) and Lecturer.

    Fall 1999: 9 graduate program (Ph.D.) students. 32 contact hours.

- PHAC 827 – Pharmacokinetics & Dose Optimization, 4 credit hours, Department of Pharmaceutical Sciences. Director and Lecturer.

  Spring 2021: 3 graduate program (Ph.D.) students. 44 contact hrs.
  Spring 2020: 4 graduate program (Ph.D.) students. 44 contact hrs.
  Spring 2019: 1 graduate program (Ph.D.) student. 44 contact hrs.
  Fall 2017: 12 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2017: 12 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2016: 11 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2015: 7 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2014: 6 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2013: 6 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2012: 8 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2011: 9 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2010: 4 graduate program (Ph.D.) students. 44 contact hrs.
  Fall 2009: 5 graduate program (Ph.D.) students. 44 contact hrs.

- PHAC 840 Section 7: Research Techniques in Pharmacokinetics, Pharmacodynamics, and Pharmacogenetics, 1 credit hour, Department of Pharmaceutical Sciences. Director.

  Fall 1999 - Spring 2014, each semester

- PHAC 840 Section 8: Population Pharmacokinetics, 1 credit hour, Department of Pharmaceutical Sciences. Director.

  Spring 2005, 2007, 2009, 2011, 2013, 2016, 2018, 2020, 2022

- PHAC 819/919 Seminars in Pharmaceutics & MEDC 819/919, Seminars in Medicinal Chemistry, 1 credit hour, Department of Pharmaceutical Sciences. Director.

  Fall 2000 - Spring 2008, each semester

- **Lincoln Memorial University, DeBusk College of Osteopathic Medicine, Harrogate, TN**

  - MFM-II Molecular Fundamentals of Medicine. Lecturer.

    Fall 2010 150 professional program (D.O.) students. 4 contact hours.
    Spring 2010 150 professional program (D.O.) students. 4 contact hours.
    Spring 2009 150 professional program (D.O.) students. 8 contact hours.
    Spring 2008 150 professional program (D.O.) students. 8 contact hours.

- **University of South Carolina, College of Pharmacy, Columbia, SC**

  - PHRM 518 - Pharmaceutics IV (Pharmacokinetics), 3 credit hours, Department of Basic Pharmaceutical Sciences. Director and Lecturer.

    Spring 1999 54 professional program (Pharm.D.) students. 55 contact hours.
    Spring 1998 60 professional program (Pharm.D.) students. 53 contact hours.

- PHRM 668 - Clinical Pharmacokinetics, 3 credit hours, Department of Clinical Pharmacy. Lecturer.

  Summer 1999 8 professional program (Pharm.D.) students. 12 contact hours.

  Fall 1998 59 professional program (Pharm.D.) students. 12 contact hours.

- PHAR 720 – Advanced Pharmacokinetics, 3 credit hours, Department of Basic Pharmaceutical Sciences. Director and Lecturer.

  Spring 1999 5 graduate program (Ph.D.) students. 49 contact hours.

- PHAR 725 – Advanced Pharmaceutics I, 2 credit hours, Department of Basic Pharmaceutical Sciences. Co-Director (with Dr. B.B. Michniak) and Lecturer.

  Fall 1998 4 graduate program (Ph.D.) students. 16 contact hours.

- **Institute for Applied Healthcare Sciences, Hamburg, Germany**
  - Workshops on Pharmacoeconomics for Clinical Pharmacists in collaboration with Dr. C.E. Reeder (1995, 1997, 1998)

- **German Society of Hospital Pharmacists - ADKA Niedersachsen, Germany**
  - Workshops on Therapeutic Drug Level Monitoring for Clinical Pharmacists (1990, 1992, 1993)

- **International Training Courses for Industrial Scientists**
  - 1st Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Data Analysis'
    Directors: Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (AstraZeneca)
    UT College of Pharmacy, Memphis, USA, April 11-15, 2011 (36 lecture hours)
    30 attendees
  - 2nd Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Data Analysis'
    Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
    UT College of Pharmacy, Memphis, USA, April 16-20, 2012 (36 lecture hours)
    46 attendees (from 8 nations)
  - 3rd Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Data Analysis'
    Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
    UT College of Pharmacy, Memphis, USA, April 15-19, 2013 (36 lecture hours)
    33 attendees (from 8 nations)
  - 4th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Data Analysis'
    Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)

UT College of Pharmacy, Memphis, USA, April 7-11, 2014 (36 lecture hours)
36 attendees (from 5 nations)

- 5th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  UT College of Pharmacy, Memphis, USA, April 13-17, 2015 (36 lecture hours)
  31 attendees (from 7 nations)

- 1st European Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  AP2POP (Organizers: Pascal Girard, Chantal Csajka), Lausanne, Switzerland, March 21-23, 2016 (24 lecture hours)
  36 attendees (from 7 nations)

- 6th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  UT College of Pharmacy, Memphis, USA, April 11-15, 2016 (36 lecture hours)
  28 attendees (from 4 nations)

- 7th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  UT College of Pharmacy, Memphis, USA, April 3-7, 2017 (36 lecture hours)
  43 attendees (from 8 nations)

- 2nd European Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  AP2POP (Organizers: Pascal Girard, Christian Laveille), Darmstadt, Germany, August 29-31, 2017 (24 lecture hours)
  27 attendees (from 7 nations)

- 8th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)

UT College of Pharmacy, Memphis, USA, April 16-20, 2018 (36 lecture hours)
47 attendees (from 4 nations)

- 3rd European Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  AP2POP (Organizers: Emilie Henin, Christian Laveille), Lyon, France, November 28-30, 2018 (24 lecture hours)
  28 attendees (from 7 nations)

- 9th Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  UT College of Pharmacy, Memphis, USA, April 1-5, 2019 (36 lecture hours)
  45 attendees (from 4 nations)

- 1st Asian-Pacific Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee) & Stacey Tannenbaum (Astellas Pharma, Chicago
  NeoTrident (Organizer: Fan Wang), Shanghai, China, May 27-29, 2019 (24 lecture hours)
  33 attendees (from 4 nations)

- 4th European Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee) & Johan Gabrielsson (Swedish University of Agricultural Sciences, Uppsala) (co-directors)
  AP2POP (Organizers: Emilie Henin, Christian Laveille), Lyon, France, November 20-22, 2019 (24 lecture hours)
  34 attendees (from 12 nations)

- 2020 Virtual Training Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee, Memphis) & Johan Gabrielsson (Biopharmacon, Gothenburg) (co-directors)
  December 2-4, 2020 (15 lecture hours)
  38 attendees (spanning live 17 time zones)

- 2021 Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee, Memphis) & Johan Gabrielsson (Biopharmacon, Gothenburg) (co-directors)
  April 11-16, 2021 (25 lecture hours)
  46 attendees

- 2021 Virtual Training Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee, Memphis) & Johan Gabrielsson (MedDoor AB, Gothenburg) (co-directors)
  December 1-3, 2021 (15 lecture hours)
  41 attendees (spanning live 17 time zones)
- 2022 Introductory Pharmacometric Training Course 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation'
  Bernd Meibohm (University of Tennessee, Memphis) & Johan Gabrielsson (MedDoor AB, Gothenburg) (co-directors)
  April 25-29, 2022 (25 lecture hours)
  45 attendees
- 2022 Virtual Training Course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics – Principles and Pharmacometric Approaches'
  Bernd Meibohm (University of Tennessee, Memphis) & Johan Gabrielsson (MedDoor AB, Gothenburg) (co-directors)
  December 5-7, 2022 (15 lecture hours)
  37 attendees

EXTERNAL REVIEWER FOR DISSERTATION/THESIS DEFENSES

- External Reviewer – Ph.D. dissertation of Ronald Niebecker, Institute of Pharmacy, Freie Universität Berlin, Germany, October 2013
- External Reviewer – Ph.D. dissertation of Vijay Nisha, Department of Pharmaceutical Sciences, University at Buffalo, Buffalo, NY, May 2014
- External Reviewer – Ph.D. dissertation of Frank Engler, Department of Pharmaceutical Sciences, University at Buffalo, Buffalo, NY, October 2015
- Faculty Opponent – Ph.D. defense of Chunli Chen, Department of Pharmaceutical Biosciences, Uppsala Universitet, Uppsala, Sweden, May 2017
- External Reviewer – Ph.D. dissertation of Helena Edlund, Institute of Pharmacy, Freie Universität Berlin, Germany, December 2017
- External Reviewer – Ph.D. dissertation of Saskia Fuhrmann, Institute of Biochemistry and Biology, Universität Potsdam, Germany, August 2018
- External Reviewer – Ph.D. dissertation of Nicholas M. Smith, University at Buffalo, State University of New York, Buffalo, NY, December 2020
- External Reviewer – Ph.D. dissertation of Ana-Marija Grisic, Institute of Pharmacy, Freie Universität Berlin, Germany, January 2021

EXTERNAL REVIEWER FOR GRADUATE PROGRAMS

- External Reviewer – M.S. program in Pharmacometrics, School of Pharmacy and Pharmaceutical Sciences, University at Buffalo/SUNY, Buffalo, NY, July 2017

- External Reviewer – Ph.D. and M.S. program in Pharmaceutical Sciences, James L. Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH, August 2018
- External Reviewer – Ph.D. and M.S. program in Pharmaceutical Sciences, School of Pharmacy, University of Mississippi, Oxford, MS, July 2019

LEGAL EXPERIENCE

- Scientific Expert Witness, University of Tennessee Health Science Center, January 2016

VISITING PROFESSORSHIPS, INVITED LECTURES AND ORAL PRESENTATIONS

1. **Meibohm, B**: 'Therapeutic Drug Monitoring of Antiarrhythmics'. Invited seminar, ADKA Niedersachsen, Northeim, Germany, September 11, 1990.
2. **Meibohm, B**: 'Drug Monitoring of Antiarrhythmics', Invited seminar, Pharmazie-Kolloqium - ICI-Pharma, Hannover, Germany, December 7, 1990.
3. **Meibohm, B**: 'Basic Pharmacokinetics', Invited seminar, Bildungsvereinigung Arbeit und Leben Niedersachsen e.V., Moringen, Germany, January 22, 1991.
4. **Meibohm, B**: 'Emergency Toxicology in Hospital Pharmacies', Guest lecture, Institute of Pharmaceutical Technology, Technical University Carolo-Wilhelmina, Braunschweig, Germany, February 7, 1991.
5. **Meibohm, B**: 'Theory and Practice of Therapeutic Drug Level Monitoring', Invited seminar, ADKA Niedersachsen, Northeim, Germany, March 4, 1992.
6. **Meibohm, B**: 'Drug Monitoring with the Software Package Mediware MW\Pharm: Diversity without Limits !?', Invited seminar, 19. Pharmacy-Colloquium, Fresenius AG, Hannover, Germany, October 9, 1992.
7. **Meibohm, B**: 'Clinical Pharmacokinetics Part II - Practice', Guest lecture, Institute of Pharmaceutical Technology, Technical University Carolo-Wilhelmina, Braunschweig, Germany, February 9, 1993.
8. **Meibohm, B**: 'Theory and Practice of Therapeutic Drug Level Monitoring', Invited seminar, ADKA Niedersachsen, Northeim, Germany, June 26, 1993.
9. **Meibohm, B**: 'Theophylline - Clinical Pharmacokinetics', Invited lecture, FOCUS Clinical Drug Development GmbH, Neuss, Germany, October 16, 1993.
10. **Meibohm, B**: 'Theory and Praxis of Therapeutic Drug Level Monitoring', Invited seminar, ADKA Niedersachsen, Northeim, Germany, December 11, 1993.
11. **Meibohm, B**, Kleine, P, Führer, C: 'Investigations on the Stereoselective Pharmacokinetics of Mexiletine during Chronic Oral Therapy', Oral presentation, 2nd European Congress of Pharmaceutical Sciences, Humboldt-University, Berlin, Germany, October 1, 1994.
12. **Meibohm, B**: 'Enantioselective Analytics of Racemic Drugs in Biological Matrices with Mexiletine and its Metabolites as Example', Guest lecture, Institute of Pharmaceutical Chemistry, Technical University Carolo-Wilhelmina, Braunschweig, Germany, December 8, 1994.

13. **Meibohm, B**: 'Pharmaceutical Service TPN', Invited seminar, Harburger Future Forum for Health, ADKA (German Hospital Pharmacists Association), Hamburg, Germany, February 4, 1995.
14. Cooke, J, **Meibohm, B**: 'Pharmacoeconomy in Oncology', Workshop in cooperation with J. Cooke, Manchester, UK, 4th International Symposium on Oncology Pharmacy Practice (ISOPP), Hamburg, Germany, May 5, 1995.
15. **Meibohm, B**, Garms, T, Meier, K, Melzer, S: 'Pharmacoeconomic Benefit of the Implementation of a Patient Oriented Automated Drug Distribution System in Combination with Intensive Advisory Services', Oral presentation, 1st International Conference on New Areas in Pharmaceutical Research, Oporto, Portugal, September 21, 1995.
16. **Meibohm, B**: 'CYPRO - The Software for Compounding Cytotoxic Drugs', Invited seminar, Pharmacy Task Force, Baxter Healthcare, Chicago, USA, June 12, 1996.
17. Reeder, CE, **Meibohm, B**: 'Designing a Pharmacoeconomic Evaluation: Principles and Methods', Workshop in cooperation with Dr. C.E. Reeder, Columbia, SC, 5th North German Cytotoxics Workshop, Hamburg, Germany, February 8, 1997.
18. Derendorf, H, Doehring, P, **Meibohm, B**: 'Clinical Pharmacokinetics and Drug Monitoring', Workshop, University of Münster, Germany, May 22-23, 1997.
19. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic Modeling of Inhaled Corticosteroids', Invited presentation, 1st Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, University of Münster, Germany, May 24, 1997.
20. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling of Inhaled Corticosteroids', Invited seminar, College of Pharmacy, University of South Carolina, Columbia, SC, June 5, 1997.
21. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling of Inhaled Corticosteroids', Oral presentation, The Seventeenth Annual Meeting of the Graduate Research Association of Students in Pharmaceutics (GRASP '97), University of Florida, Gainesville, Florida, June 7, 1997.
22. **Meibohm, B**: 'Differences in the Pharmacokinetics and Pharmacodynamics of Inhaled Corticosteroids', Invited seminar, University of Florida Health Science Ctr, Pharmacodynamics & Pharmaceutics Seminar Series, Gainesville, FL, September 25, 1997.
23. Reeder, CE, **Meibohm, B**: 'Pharmacoeconomic Analysis: Principles, Methods and Examples', Workshop in cooperation with Dr. C.E. Reeder, Columbia, SC, 6th North German Cytotoxics Workshop, Hamburg, Germany, January 24, 1998.
24. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling: Principles and Applications', Invited Seminar, University Clinic Eppendorf, Pharmacological Institute, University of Hamburg, Hamburg, Germany, May 19, 1998.
25. **Meibohm, B**: 'Pharmacokinetic Assessment of Absorption Parameters - Methods and Pitfalls', Invited seminar, Clinical Research & Development / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, July 29, 1998.

26. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic Modeling of Cytotoxic Drugs - Principles and Examples', Invited seminar, Clinical Research & Development / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, July 30, 1998.
27. **Meibohm, B**: 'Concepts of Modeling Pharmacokinetic/Pharmacodynamic Relationships and their Application to Inhaled Corticosteroids', Invited seminar, Department of Pharmaceutical Sciences, College of Pharmacy, Medical University of South Carolina, Charleston, SC, November 5, 1998.
28. **Meibohm, B**: 'Inhaled Corticosteroid Therapy as an Example for Applied PK/PD-Modeling', Invited seminar, Department of Pharmaceutical Sciences, College of Pharmacy, University of Tennessee, Memphis, TN, March 9, 1999.
29. **Meibohm, B**: 'Application of PK/PD-Modeling Concepts for Cytotoxic Drugs', invited seminar, ASTA Medica AG, Frankfurt, Germany, June 1, 1999.
30. **Meibohm, B**: 'Classification of PK/PD-Modeling Approaches', Invited presentation, 2nd Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, University of Reims - Champagne Ardenne, France, June 5, 1999.
31. **Meibohm, B**: 'Dose Individualization of Cytotoxics Based on Pharmacokinetic and Pharmacodynamic Concepts', Invited presentation, 8th North German Cytotoxics Workshop, Hamburg, Germany, January 29, 2000.
32. **Meibohm, B**: 'Gender Differences in Pharmacokinetics and Pharmacodynamics – Do They Matter ? invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, May 18, 2000.
33. **Meibohm, B**: 'Update on the Clinical Pharmacology of Gantofiban', Invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, May 18, 2000.
34. **Meibohm, B**: 'Preclinical Pharmacokinetics and Pharmacodynamics of EMD 221 829 in Dogs', Invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, May 19, 2000.
35. **Meibohm, B**: 'Pharmacogenetics in Cancer Chemotherapy', Invited Presentation, 9th North German Cytotoxics Workshop, Hamburg, Germany, January 27, 2001.
36. **Meibohm, B**: 'Screening for Pharmacodynamic Response Markers in COPD by cDNA-Microarrays', Invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, June 13, 2001.
37. **Meibohm, B**: 'Pharmacokinetic/Pharmacodynamic Studies in Drug Product Development', Invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, June 13, 2001.
38. **Meibohm, B**: 'Screening for Pharmacodynamic Response Markers in COPD by cDNA-Microarrays', Oral presentation, 3rd Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Dresden, Germany, June 16, 2001.
39. **Meibohm, B**: 'Developmental Pharmacokinetics and Pharmacodynamics in Pediatric Cardiology', Invited presentation, Department of Pharmaceutical Sciences, College of Pharmacy, University of Arkansas for Medical Sciences, Little Rock, AR, November 9, 2001.

40. Hochhaus, G, **Meibohm, B**: 'Clinical Pharmacokinetics and Pharmacodynamics – Introduction to PK-PD Modeling', One-Day Interactive Seminar, Institute for International Research, Pharmaceutical Division, Philadelphia, PA, March 11, 2002.
41. **Meibohm, B**: 'Overview of Drug Transport', Invited presentation, 8th International Symposium on Oncology Pharmacy Practice, Vancouver, Canada, May 9, 2002.
42. **Meibohm, B**: 'P-gp Drug Interactions in Oncology', Invited presentation, 8th International Symposium on Oncology Pharmacy Practice, Vancouver, Canada, May 9, 2002.
43. **Meibohm, B**: 'Drug Transporters as a Source of Interindividual Variability in Drug Response', Invited seminar, Department of Pharmaceutical Sciences, College of Pharmacy, University of Tennessee, Memphis, TN, August 26, 2002.
44. **Meibohm, B**: 'Effect of MDR1 Genetic Polymorphisms on Drug Disposition', Invited seminar, Clinical R&D Operations / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, November 7, 2002.
45. **Meibohm, B**: 'Application of PK/PD-Concepts for Efficient Drug Development', Invited presentation, VKliPha 4th Annual Congress on Clinical Pharmacology, Wiesbaden, Germany, November 9, 2002.
46. **Meibohm, B**: 'Exposure-Response vs. Dose-Response Assessments in Drug Development', Invited presentation, Annual Congress of the Association for Applied Human Pharmacology (AGAH), Bonn, Germany, February 23-25, 2003.
47. **Meibohm, B**, Gupta, M, Freire, AX, Wicks, MN, Tolley, EA, Yates, CR. 'cDNA Array Analysis Indicates Upregulation of CXCR2 and CXCR5 Expression in COPD', Oral presentation, 99th International Conference, American Thoracic Society, Seattle, WA, May 21, 2003.
48. **Meibohm, B**: 'Molecular & Genetic Factors in COPD', Invited lecture, Pulmonary Medicine Series – Obstructive and Genetic Lung Diseases, University of Tennessee College of Medicine, Division of Pulmonary & Critical Care Medicine, Memphis, TN, September 9, 2003.
49. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics in Drug Dose Administration Schemes', Visiting Professorship, 90. Nephrology Forum Munich, Ludwig-Maximilian-University, Munich, Germany, November 24, 2003.
50. **Meibohm, B**: 'How Important are Sex Differences in Pharmacokinetics?', Invited Presentation, Fifth Annual Conference on Sex and Gene Expression (SAGE V), Society for Women's Health Research, Graylyn Conference Center, Winston-Salem, NC, March 27, 2004.
51. **Meibohm, B**: 'Introduction to PK/PD-Modeling', Invited seminar, Clinical Pharmacokinetics / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, April 21, 2004.
52. **Meibohm, B**: 'How Important are Sex Differences in Pharmacokinetics?', Invited seminar, Clinical Pharmacokinetics / Clinical Pharmacology, Merck KGaA, Darmstadt, Germany, April 22, 2004.
53. **Meibohm, B**: 'Pharmacokinetics of Oligonucleotides', Invited presentation, VKliPha (German Clinical Pharmacology Association) 9th Annual PK/PD Expert Meeting, Freiburg, Germany, April 24, 2004.

54. **Meibohm, B**: 'PK/PD Modeling as the Basis for the Development and Validation of Biomarkers', Invited Presentation, AAPS Workshop: Clinical Biomarkers in Drug Development: Efficacy Assessment, Pharmacokinetics/Pharmacodynamics and Regulatory Insights, Baltimore, MD, November 5, 2004.
55. **Meibohm, B**: 'Developmental Changes in Molecular Mechanisms of Pediatric Drug Disposition', Invited presentation, 5th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Leuven, Belgium, June 4, 2005.
56. **Meibohm, B**: 'Clinical Pharmacology and Pharmacy of Oligonucleotides Drug Candidates', Invited presentation, PharmSciFair Pharmaceutical Sciences Fair & Exhibition, Nice, France, June 13, 2005.
57. **Meibohm, B**: 'Biomarkers in Pharmacokinetic/Pharmacodynamic Modeling to Integrate Expose/Response', Invited presentation, AAPS Workshop: Integrated Roadmap to Biomarker for Drug Development – Method Validation and Qualification, Rockville, MD, September 9, 2005.
58. **Meibohm, B**: 'Population Pharmacokinetic Studies: Issues in Design and Analysis', Invited presentation, Johnson& Johnson Pediatrics Symposium – Not Just Child's Play: The Impact of Modeling & Simulation in Pediatric Drug Development, Bridgewater, NJ, October 17, 2005.
59. **Meibohm, B**: 'Genetics of COPD', Invited lecture, University of Tennessee College of Medicine, Division of Pulmonary & Critical Care Medicine, Memphis, TN, October 27, 2005.
60. **Meibohm, B**: 'Introduction to Modeling & Simulation', Invited presentation, American Association of Pharmaceutical Scientists AAPS 2005 Annual Meeting, Nashville, TN, November 6, 2005.
61. **Meibohm, B**: 'Applying Biological Rhythms in Timing of Medication: Glucocorticoids as an Example', Invited presentation, Neuroendocrine Immunology Study Group, American College of Rheumatology ACR 69th/ARHP 40th Annual Scientific Meeting, San Diego, CA, November 14, 2005.
62. **Meibohm, B**: 'Evaluation of Pharmacokinetic Metrics for a Pharmacogenetic Study', Invited presentation, Association for Applied Human Pharmacology/American College of Clinical Pharmacology AGAH/ACCP Workshop on Computer Simulation and its Role in Drug Development, Düsseldorf, Germany, February 18-19, 2006.
63. **Meibohm, B**: 'Interplay between Drug Metabolizing Enzymes and Drug Transporters', Invited presentation, Association for Applied Human Pharmacology/American College of Clinical Pharmacology AGAH/ACCP 2nd Joint Meeting – Transatlantic Strategies in Early Drug Development, Düsseldorf, Germany, February 19-21, 2006.
64. **Meibohm, B**: 'Developmental Changes in Pediatric Drug Disposition and Response', Visiting Professorship - Pfizer Lecture Series, Department of Pharmaceutical Sciences, University of Michigan College of Pharmacy, Ann Arbor, MI, March 22, 2006.
65. **Meibohm, B**: 'Biomarkers and PK/PD Modeling: A Match Made in Heaven!', Invited presentation, Pfizer Inc. Global Research & Development, Ann Arbor, MI, March 23, 2006.

66. **Meibohm, B**: 'Biomarkers as Prerequisite for PK/PD Modeling and Model-Based Drug Development', Invited presentation, Clinical Biomarker Summit, Cambridge Healthtech Institute, San Diego, CA, March 29-31, 2006.
67. **Meibohm, B**: 'Introduction to the Quantitative Pharmacology (QX Initiative) of AAPS', Invited presentation, American Association of Pharmaceutical Scientists AAPS 2006 Annual Meeting, San Antonio, TX, October 31, 2006.
68. **Meibohm, B**: 'Predictors of Mortality in Elderly Subjects with Obstructive Airway Disease: Modeling in Epidemiology', Invited presentation, 6th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Munich, Germany, June 9, 2007.
69. **Meibohm, B**: 'PK/PD Evaluation of Biologics: Challenges and Pitfalls, Invited Presentation, AstraZeneca R&D, Mölndal, Sweden, June 11, 2007.
70. **Meibohm, B**: 'Biotechnological Medications: Pharmacokinetic and Pharmacodynamic Peculiarities', Invited seminar, Division of Clinical Pharmacy & Pharmacotherapy, Heinrich-Heine-University & German Pharmaceutical Society (DPhG), Düsseldorf, Germany, June 14, 2007.
71. **Meibohm, B**: 'Pharmacogenetics in Pulmonary Diseases', Invited lecture, University of Tennessee College of Medicine, Division of Pulmonary & Critical Care Medicine, Memphis, TN, September 25, 2007.
72. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Biologics: Challenges and Pitfalls', Invited lecture, 10th Annual Symposium on Chemical and Pharmaceutical Structure Analysis, Langhorne, PA, October 25, 2007.
73. **Meibohm, B**: 'Biological Drug Development - from an Academic Perspective', Invited lecture, International Symposium on Quantitative Pharmacology in Drug Development and Regulation, Nanjing, China, October 30, 2007.
74. **Meibohm, B**: 'Simulation Techniques in Adult Drug Development', Invited lecture, HEXAL-Initiative Pediatric Drugs – Expert Workshop 'The "*in silico* child" or Can we calculate children?', Düsseldorf, Germany, February 14, 2008.
75. **Meibohm, B**: 'Evaluation of Vancomycin Dosing Regimens in Preterm and Term Neonates using Monte-Carlo Simulations', Invited lecture, HEXAL-Initiative Pediatric Drugs – Expert Workshop 'The "*in silico* child" or Can we calculate children?', Düsseldorf, Germany, February 14, 2008.
76. **Meibohm, B**: 'Special Requirements for Biotech Drugs – A Challenge for the Pharmacist of the 21st Century', Invited lecture, 1st Alumni Symposium of the Division of Pharmacy at the Heinrich-Heine University, Düsseldorf, Germany, February 16, 2008.
77. **Meibohm, B**: 'Basic Concept of PK/PD-Modeling', Invited lecture, University of Mississippi School of Pharmacy, Oxford, MS, April 15, 2008.
78. **Meibohm, B**: 'Success Stories of Model-Based Drug Development', Invited lecture, Human Pharmacology, MerckSerono S.A., Geneva, Switzerland, June 12, 2008.
79. **Meibohm, B**: 'Pharmacokinetic and Pharmacodynamic Challenges of Monoclonal Antibodies', Invited lecture, Human Pharmacology, MerckSerono S.A., Geneva, Switzerland, June 13, 2008.

80. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Biotech Drugs', Invited lecture, 9th Annual Land O'Lakes Bioanalytical Conference, University of Wisconsin Extension Services in Pharmacy, Devils Head Resort, Merrimac, WI, July 17, 2008.
81. **Meibohm, B**: 'Fundamentals of PK and PK/PD of Biologics – An Overview', Invited lecture, Rosenön Meeting 2008: Application of DMPK Principles in Evaluation of Drug Safety, Swedish Academy of Pharmaceutical Sciences, Stockholm, Sweden, September 11, 2008.
82. **Meibohm, B**: Invited lecture series: 'Pharmacokinetics of Peptides and Proteins'; 'PK and PD Challenges of Monoclonal Antibodies'; 'Exposure-Response Modeling for Biologics', Gothenburg University, Gothenburg, Sweden, October 27, 2008.
83. **Meibohm, B**: 'Clinical Pharmacology of Oligonucleotide Drug Candidates', Invited "Drug hunting lecture", AstraZeneca, Mölndal, Sweden, October 28, 2008.
84. **Meibohm, B**: 'Pharmacokinetic and Pharmacodynamic Modeling of Biologics: Understanding New Complexities', Invited lecture, AAPS Annual Meeting, Atlanta, GA, November 18, 2008.
85. Suryawanshi, S, **Meibohm, B**: 'Disease Progression Model for Lucentis in Age Related Macular Degeneration', Research presentation, Genentech Inc., San Francisco, CA, April 29, 2009.
86. **Meibohm, B**: 'The Role of PKPD in the Model-based Drug Development of Biotech Drugs', Invited presentation, Genentech Inc., San Francisco, CA, April 29, 2009.
87. **Meibohm, B**: 'Tuberculosis Drug Development: PK/PD Challenges', Invited presentation, 7th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Stresa, Italy, June 13, 2009.
88. **Meibohm, B**: 'Clinical Pharmacology of Oligonucleotide Drug Candidates', Invited presentation, F. Hoffmann-La Roche, Basel, Switzerland, June 15, 2009.
89. **Meibohm, B**, Derendorf, H, Allerheiligen, S, Cadieu, D, Joshi, A, Lalonde, R. 'Where Will The Pharmacometricians Of The Future Come From?', Roundtable discussion, American Conference on Pharmacometrics (ACoP), Mashantucket, CT, October 4-7, 2009.
90. **Meibohm, B**: 'Ontogeny of Drug Metabolizing Enzymes and Transporters: Potential Biomarkers for Drug Disposition in Newborns and Infants', Invited presentation, AAPS/ACCP Symposium, AAPS Annual Meeting, Los Angeles, CA, November 9, 2009.
91. **Meibohm, B**: 'The Impact of Exploratory Medicine on NBE Development – Part I, Invited presentation, MerckSerono, Frankfurt, Germany, April 26, 2010.
92. **Meibohm, B**: 'The Impact of Exploratory Medicine on NBE Development – Part II, Invited presentation, MerckSerono, Frankfurt, Germany, April 26, 2010.
93. **Meibohm, B**. 'Pharmacokinetic and Pharmacodynamic Modeling of Biologics: Understanding New Complexities', AAPS Webinar, 425 live attendees in 12 countries, April 29, 2010.
94. **Meibohm, B**: 'Pharmacokinetics of Protein Therapeutics: Impact of Immunogenicity', Invited presentation, AAPS National Biotechnology Conference, San Francisco, CA, May 19, 2010.

95. **Meibohm, B**: 'Clinical Pharmacology Development Strategy for Therapeutic Proteins', Invited presentation, 39th Annual Meeting, American College of Clinical Pharmacology, Baltimore, MD, September 13, 2010.

96. **Meibohm, B:** 'Methodology: Top Down vs. Bottom Up Approach in Modeling and Simulation: What can we achieve with which method?, Expert Workshop on the In Silico Child, September 28–29, 2010, Genova, Italy

97. **Meibohm, B**. 'Complexities in the Pharmacokinetic and Pharmacodynamic Evaluation of Protein Therapeutics', Webinar, AstraZeneca Global Sites, November 2, 2010.

98. **Meibohm, B**: 'PK and PD Challenges of Monoclonal Antibodies', Invited presentation, AstraZeneca, Gothenburg, Sweden, January 31, 2011.

99. **Meibohm, B**: 'PK/PD Challenges in Tuberculosis Drug Development', Invited presentation, University of Pittsburgh School of Pharmacy, February 23, 2011.

100. **Meibohm, B**: 'PK/PD Challenges in the Development of Protein Therapeutics', Invited presentation, F. Hoffmann-La Roche, Basel, Switzerland, March 31, 2011.

101. **Meibohm, B**: 'Clinical Pharmacology Development Strategy for Protein Therapeutics', Invited presentation, Merck KGaA, Darmstadt, Germany, June 6, 2011.

102. **Meibohm, B**: 'The In Silico Child: PK/PD Modeling in Pediatric Drug Development', New England Drug Metabolism Discussion Group, Shrewsbury, MA, June 14, 2011.

103. **Meibohm, B**: 'Applications of PK/PD Modeling in the Development of Protein Therapeutics', Invited lecture, PKDM department, Amgen, Thousand Oaks, CA, August 16, 2011.

104. **Meibohm, B**: 'Applications of PK/PD Modeling in the Development of Protein Therapeutics', Visiting Professor Lecture Series, Office of clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD, August 30, 2011.

105. **Meibohm, B:** 'Developmental Pharmacology', Seminar 'Pharmacokinetics & Pharmacodynamics in Pediatrics', Genoa, Italy, September 29-30, 2011.

106. **Meibohm, B:** 'Modeling & Simulation and PK/PD: Top Down vs. Bottom Up Approach -What Can We Achieve With Which Method?', Genoa, Italy, September 29-30, 2011.

107. **Meibohm, B:** 'Study Designs Applied to Population Pharmacokinetics, Seminar 'Pharmacokinetics & Pharmacodynamics in Pediatrics', Genoa, Italy, September 29-30, 2011.

108. **Meibohm, B:** 'Application of PK/PD Modeling in the Development of Protein Therapeutics, Quotient Bioresearch Autumn Seminar, Fordham/Cambridge, October 5, 2011.

109. **Meibohm, B**: 'Basic Principles of Pharmacokinetics and Pharmacodynamics of Biologics', Invited Presentation, 25th AAPS Annual Meeting, Washington, DC, October 23, 2011.

110. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics, Invited 2-day lecture series, AstraZeneza, Södertälje, Sweden, January 9-10, 2012.

111. **Meibohm, B**: 'Protein Therapeutics in Oncology: Relevance of Pharmacokinetics and Pharmacodynamics for Applied Therapy', Plenary lecture, 20th North German Cytotoxics Workshop, Hamburg, Germany, January 29, 2012.

112. **Meibohm, B:** 'Developmental Pharmacology', Invited lecture, Workshop 'Facilitating Pediatric Research with Modeling and Simulation', Children's Hospital of Philadelphia, University of Pennsylvania, Philadelphia, PA, April 23, 2012.

113. **Meibohm, B:** 'Mechanistic Basis for Potential Drug-Drug Interactions with Therapeutic Proteins', Plenary lecture, Workshop on 'Recent Advances in the Investigation of Therapeutic Protein Drug-Drug Interactions: Preclinical and Clinical Approaches', U.S. Food and Drug Administration and IQ Consortium, Silver Spring, MD, June 4, 2012.

114. **Meibohm, B:** 'Utility of PK and PD in Biologics Drug Development, including Biosimilars', Invited lecture, Office of Clinical Pharmacology, Center for Drug Evaluation and Research. U.S. Food and Drug Administration, Silver Spring, MD, August 6, 2012.

115. **Meibohm, B:** 'Drug-Drug-Interactions for Large Molecules and their Assessment in Drug Development', Invited lecture, Amgen Inc., Thousand Oaks, CA, August 15, 2012.

116. **Meibohm, B:** 'Modeling & Simulation in Pediatrics', Invited Lecture, 1st World Conference on Pharmacometrics, Seoul, Korea, September 7, 2012.

117. **Meibohm, B:** 'Pharmacokinetics and Pharmacodynamics of Therapeutic Proteins', Invited lecture, Yonsei University, College of Pharmacy, Seoul, Korea, September 10, 2012.

118. **Meibohm, B:** 'Drug Disposition of Therapeutic Proteins', Invited lecture, University of Florida College of Pharmacy, Lake Nona campus, Orlando, FL, October 5, 2012.

119. **Meibohm, B:** 'The *In Silico* Child: PK/PD Modeling and Simulation in Pediatric Pharmacotherapy', Invited lecture, University of Florida College of Pharmacy, Gainesville campus, Gainesville, FL, October 6, 2012.

120. **Meibohm, B**: 'The *In Silico* Child: Modeling and Simulation in Support of Developing Age-Appropriate Pediatric Dosing Recommendations', Invited lecture, Universitätskinderspital beider Basel, Basel, Switzerland, January 21, 2013.

121. **Meibohm, B**: 'Complexity of Human PK/PD of Monoclonal Antibodies'. Invited lecture, Health Canada, Ottawa, Canada, February 5, 2013.

122. **Meibohm, B**: 'PK/PD Modeling in the Development of Therapeutic Protein'. Guest lecturer. Virginia Commonwealth University School of Pharmacy, Richmond, VA, February 20, 2013.

123. **Meibohm, B**: 'Translational Approaches to Facilitate Accelerated Development of Biologics', Invited presentation, Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Indianapolis, IN, March 8, 2013.

124. **Meibohm, B**. 'Mechanistic Basis for Potential Drug-Drug Interactions with Therapeutic Proteins', Invited presentation, MedImmune, Gaithersburg, MD, March 21, 2013.

125. **Meibohm, B**: 'The Need for Model-based PKPD Approaches In the Development of Therapeutic Proteins', Invited presentation, AAPS National Biotechnology Conference, San Diego, CA, May 20, 2013.

126. **Meibohm, B**: 'Translational Approaches to Facilitate Accelerated Development of Biologics', Invited presentation, Merck KGaA, Darmstadt, Germany, May 24, 2013.

127. **Meibohm, B**. 'Drug Interactions Involving Therapeutic Biologics – What We Need to Know', Keynote lecture, 4th International Workshop on Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions, Marbach Castle, Lake Constance, Germany, May 27, 2013.

128. **Meibohm, B**: 'Clinical Pharmacology Challenges for Protein Therapeutics: Immunogenicity and Drug-Drug-Interactions', Invited presentation, AbbVie Inc., Ludwigshafen, Germany, May 29, 2013.

129. **Meibohm, B**. 'Complexity of Human PK/PD of Monoclonal Antibodies, Invited presentation, Expert Roundtable on Biosimilars to Infliximab, Janssen, Toronto, June 28, 2013.

130. **Meibohm, B**. 'New Tricks for an Old Dog: Spectinamides as Novel Anti-Tuberculosis Agents', Invited presentation, 9th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Garmisch-Partenkirchen, Germany, July 20, 2013.

131. **Meibohm, B**. 'Clinical Pharmacology Principles and Unique Considerations for Therapeutic Protein Development in Children', Invited presentation, Annual Meeting of the American College of Clinical Pharmacology, Bethesda, MD, September 22-24, 2013.

132. **Meibohm, B**. 'Pharmacokinetics and Pharmacodynamics of Therapeutic Peptides and Proteins: Opportunity for Better Therapeutics', Invited presentation, Annual Meeting of the American College of Clinical Pharmacology, Bethesda, MD, September 22-24, 2013.

133. **Meibohm, B**. 'Impact of Immunogenicity on PK/PD and Efficacy of Biotherapeutics', Invited presentation, Annual Meeting of the American College of Clinical Pharmacology, Bethesda, MD, September 22-24, 2013.

134. **Meibohm, B**. 'Challenges in the In Vivo Disposition of Oligonucleotides', Invited presentation, AstraZeneca, Mölndal, Sweden, October 3, 2013.

135. **Meibohm, B**. 'Clinical Pharmacodynamics and PKPD Modeling & Simulation', Invited presentation, Biogen Idec, Waltham, MA, October 22, 2013.

136. **Meibohm, B**. 'Population Pharmacokinetics', Invited presentation, Biogen Idec, Waltham, MA, October 22, 2013.

137. **Meibohm, B**. 'Quantitative Pharmacology & Pharmacometrics: Principles & Application in R&D', MerckSerono, Drug Development Curriculum, Online recorded, Darmstadt, Germany, October 29, 2013.

138. **Meibohm, B**. 'PK/PD Considerations for Biosimilar Monoclonal Antibodies', Invited presentation, Health Canada, Ottawa, November 4, 2013.

139. **Meibohm, B**. 'Mechanisms & Challenges in the Assessment of Interferences between Immunogenicity and Pharmacokinetics'. Invited presentation, AAPS Annual Meeting, San Antonio, TX, November 11, 2013.

140. **Meibohm, B**. 'Complexity of PKPD for Therapeutic Proteins'. Invited presentation and Invited Meeting Chair, Janssen Subsequent Entry Biologics PKPD Advisory Board, Toronto, CA, December 19, 2013.

141. **Meibohm, B**. 'Complexity of PKPD for Therapeutic Proteins'. Invited presentation and Invited Meeting Chair, 2014 Winter Symposium, Research Triangle Park Drug Metabolism Discussion Group, Durham, NC, February 20, 2014.

142. **Meibohm, B**: 'Covariates in the Utilization and Management of Therapy with Biologics in Oncology', Invited presentation, AAPS National Biotechnology Conference, San Diego, CA, May 19, 2014.

143. **Meibohm, B**: 'Current practice in dosing biologics in children and how PBPK models can help', Invited presentation, AAPS National Biotechnology Conference, San Diego, CA, May 19, 2014.

144. **Meibohm, B**: 'David and Goliath: Pediatric Pharmacokinetics of Small Molecules versus Biologics', Invited presentation, AAPS National Biotechnology Conference, San Diego, CA, May 20, 2014.

145. **Meibohm, B**: 'Challenges and Pitfalls of Scientific Publishing in the 21st Century', Invited presentation, University of Tennessee College of Pharmacy, Memphis, TN, May 29, 2014.

146. **Meibohm, B**: 'Meibohm, B: 'Workshop on PK and PK/PD of Protein Therapeutics', Invited presentations, Boehringer Ingelheim, Biberach, Germany, June 30, 2014.

147. **Meibohm, B**: 'Challenges in Early Clinical Development of Therapeutic Proteins for Oncology', Invited presentation, Merck KGaA, Darmstadt, Germany, July 2, 2014.

148. **Meibohm, B**: 'Translational Considerations in Developing Bispecific Antibodies: What can we learn from Mechanism PKPD Modeling?', Invited Presentation, 2014 Annual Meeting of the American College of Clinical Pharmacology, Atlanta, GA, September 15, 2014.

149. **Meibohm, B**: 'Ontogeny of Disposition Processes, with Focus on Hepatic Transport - Potential Biomarkers for Drug Disposition in Newborns and Infants'. Invited lecture, The Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 2014-2015 Principles of Pediatric Clinical Pharmacology Course, Live webinar, October 7, 2015.

150. **Meibohm, B**: 'New Tricks of an Old Dog: Applications of PKPD Concepts in Drug Development', Invited presentation, Genentech Inc., South San Francisco, CA, October 17, 2014.

151. **Meibohm, B**: 'PK/PD Need/Value of Looking at Catabolic Breakdown Products for Protein Therapeutics', Invited presentation, AAPS Annual Meeting, San Diego, CA, November 5, 2014.

152. **Meibohm, B,** Gabrielsson, J. 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics', Invited training course, Merck & Co, North Wales, PA, January 20-21, 2015.

153. **Meibohm, B**: 'State-of-the-Art Science in Clinical Pharmacology to Support Drug Discovery and Development: Vision 2020', Keynote lecture, 8th Annual Conference –

South Asian Chapter of the American College of Clinical Pharmacology, Mumbai, India, April 24-25, 2015.

154. **Meibohm, B**: 'Scientific background of PK/PD modelling', Workshop presentation, EUFEMED Joint Conference of the European Human Pharmacological Societies, Brussels, Belgium, May 20-22, 2015.

155. **Meibohm, B**: 'Drug-drug interactions between biologicals and small molecules', Invited presentation, EUFEMED Joint Conference of the European Human Pharmacological Societies, Brussels, Belgium, May 20-22, 2015.

156. **Meibohm, B**: 'Challenges in Establishing Pediatric Dosing Recommendations for Small Molecules versus Biologics', Merck KGaA, Darmstadt, Germany, May 18, 2015.

157. **Meibohm, B**: 'Therapeutic proteins - Huge promises but how to deal with them for paediatric patients ', Invited lecture, 2015 Congress of the European Society for Developmental Perinatal and Paediatric Pharmacology, Belgrade, Serbia, June 23-26, 2015.

158. **Meibohm, B**: 'Clinical Pharmacology of Protein-Engineered Antibody Constructs', Invited presentation, 10th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Utrecht, The Netherlands, June 6, 2015.

159. **Meibohm, B**: 'Impact of Immunogenicity on PK/PD & Efficacy of Biotherapeutics', Invited presentation, Sanofi Deutschland, Frankfurt, June 26, 2015.

160. **Meibohm, B**: 'Opportunities for Model-Based Drug Development', Invited presentation, Sanofi Deutschland, Frankfurt, June 26, 2015.

161. **Meibohm, B**: 'Therapeutic Protein PKPD Workshop', Invited workshop, Boehringer Ingelheim, Biberach, June 29-30, 2015.

162. **Meibohm, B**. 'Confounding Effect of Disease State on the Pharmacokinetics and Efficacy of Oncology Drugs', Invited presentation, 2015 Annual Meeting of the American College of Clinical Pharmacology, San Francisco, CA, September 29, 2015.

163. **Meibohm, B**. 'Therapeutic Protein Disposition: An Old Dog with New Tricks', Invited short course presentation, 20th North American Meeting of the International Society for the Study of Xenobiotics, Orlando, FL, October 18, 2015.

164. **Meibohm, B**. 'Translational Considerations in Developing Bispecific Antibodies – What Can We Learn from Mechanistic PK/PD Modeling', Invited presentation, ASCPT-AAPS Symposium, AAPS Annual Meeting, Orlando, FL, October 27, 2015.

165. **Meibohm, B**. 'Effect of Disease State on the Pharmacokinetics and Efficacy of Therapeutic Proteins used in Oncology', Invited presentation, 24th North German Cytotoxics Workshop (NZW), European Society for Oncology Pharmacy, Hamburg, Germany, January 29, 2016.

166. **Meibohm, B**. 'Dose-Response: The Confluence of Disease, Endpoints, Pharmacology, Modality and their Impact', Invited presentation, ASCPT Annual Meeting, San Diego, CA, March 10, 2016.

167. **Meibohm, B.** 'International Certificate Course on PK/PD', Invited course, Bombay College of Pharmacy & Indian Council of Medical Research, Mumbai, India, April 26-27, 2016.

168. **Meibohm, B**: 'Ontogeny of Drug Metabolizing Enzymes & Drug Transporters in Pediatric Drug Development and Pharmacotherapy, 'Invited lecture, 9th Annual Conference – South Asian Chapter of the American College of Clinical Pharmacology, Mumbai, India, April 29-30, 2016.

169. **Meibohm, B**: 'Pharmacometrics and Quantitative Pharmacology: A Framework for the Successful Development of Therapeutic Proteins', Invited lecture, III.rd Congress of the Brazilian Association of Pharmaceutical Sciences, Porto Alegre, Brazil, June 13-15, 2016.

170. **Meibohm, B**: 'Complexity of PK/PD of Protein Therapeutics', Invited Workshop, Institut für Pharmazie, Freie Universität Berlin, Germany, July 19, 2016.

171. **Meibohm, B**: 'Confounding Effect of Disease State on the Pharmacokinetics and Efficacy of Therapeutic Proteins', Invited lecture, Sanofi, Frankfurt, July 21, 2016.

172. **Meibohm, B**: 'Clinical Pharmacology Challenges in the Development of Therapeutic Proteins', Invited lecture, Bayer Pharma, Wuppertal, Germany, July 22, 2016.

173. **Meibohm, B**: 'Translational Considerations in Developing Bispecific Antibodies: What Can We Learn From Mechanistic PK/PD Modeling?' Invited lecture, 2016 Annual Meeting of the American College of Clinical Pharmacology, Bethesda, MD, September 24, 2016.

174. **Meibohm, B**: 'Dose-Exposure-Response Analysis of Spectinamide Antibiotic Lee 1810 in Mycobacterium tuberculosis Infected Mice', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 23, 2017.

175. **Meibohm, B**: 'Therapeutic Proteins: Huge Promises but how to deal with them for Pediatric Patients?', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 23, 2017.

176. **Meibohm, B**: 'Confounding Effect of Disease State on the Pharmacokinetics and Efficacy of Therapeutic Proteins used in Oncology', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 23, 2017.

177. **Meibohm, B**: 'Therapeutic Protein PKPD Workshop', Invited Workshop, Boehringer Ingelheim US, Ridgefield, CT, April 27-28, 2017.

178. **Meibohm, B**: 'Challenges in the Assessment of the Exposure-Response Relationship of Therapeutic Proteins When Exposure is a Function of Response', Invited Seminar, Department of Pharmaceutical Biosciences, Uppsala Universitet, Uppsala, Sweden, May 18, 2017.

179. **Meibohm, B**: 'PKPD Modeling in Biosimilar Drug Development', Invited Seminar, Biocon Research Limited, Bangalore, India, August 18, 2017.

180. **Meibohm, B**: 'Challenges in Exposure-Response Assessment for Therapeutic Proteins When Exposure is a Function of Response', Invited Seminar, Mini-Symposium on Overcoming Pharmacology Barriers in Drug Development, Merck KGaA, Darmstadt, Germany, August 28, 2017.

181. **Meibohm, B**: 'The Millennial Clinical Pharmacologist: How to Tackle the Brave New World', Invited award presentation, Annual meeting of the American College of Clinical Pharmacology, San Diego, CA, September 18, 2017.

182. **Meibohm, B**: 'Challenges in Exposure-Response Assessment for Therapeutic Proteins When Exposure is a Function of Response', Invited Seminar, Sanofi, Bridgewater, NJ September 21, 2017.

183. **Meibohm, B**: 'Challenges in Exposure-Response Assessments for Therapeutic Protiens When Exposure is a Function of Response, Keynote Presentation, Merck Translational PKPD/Model-Informed Drug Discovery Symposium 2017, Merck & Co., Upper Gwynedd, PA, October 23, 2017.

184. **Meibohm, B**: 'Immunogenicity Challenges in the Preclinical and Clinical Development of Novel Biotherapeutics', Invited Lecture, The Genomics Institute of the Novartis Research Foundation, San Diego, CA, November 10, 2017.

185. **Meibohm, B**. 'Challenges in the Exposure-Response Assessment of Antibody-Based Oncology Agents', Invited presentation, 26th North German Cytotoxics Workshop (NZW), European Society for Oncology Pharmacy, Hamburg, Germany, January 26, 2018.

186. **Meibohm, B**: 'PK/PD Modelling and Simulation of Therapeutic Proteins: Rapid Equilibrium and Distribution', Invited lecture, PharMetriX Workshop, Institut für Pharmazie, Freie Universität Berlin, Germany, January 29, 2018.

187. **Meibohm, B**: 'The Immunogenicity Challenges in the Preclinical and Clinical Development of Novel Biotherapeutics', Invited lecture, PharMetriX Workshop, Institut für Pharmazie, Freie Universität Berlin, Germany, January 29, 2018.

188. **Meibohm, B**: 'MAbs: Drug disposition and tissue distribution', Invited lecture, PharMetriX Workshop, Institut für Pharmazie, Freie Universität Berlin, Germany, January 29, 2018.

189. **Meibohm, B**: 'Application of Pharmacometric Approaches in the Preclinial Development of Novel Antibiotics Against Tuberculosis', Invited seminar, University of Maryland School of Pharmacy, Baltimore, MD, March 28, 2018.

190. **Meibohm, B**: 'Application of Pharmacometrics in the Preclinical Development of Novel Antibiotics Against Tuberculosis', Invited seminar, University of Florida College of Pharmacy, Gainesville, FL, April 30, 2018.

191. **Meibohm, B**: 'Unexpected Challenges in the Pharmacokinetic Characterization of Novel Biologics', Keynote presentation, EMBL-EBI Workshop on 'Pharmacokinetics (PK) Prediction and Design for Biologics', European Bioinformatics Institute, Welcome Trust Genome Campus, Cambridge, UK, June 27, 2018.

192. **Meibohm, B**: 'Discovery and Preclinical Development of Spectinamides, a Novel Class of Anti-Tuberculosis Agents', Invited presentation, International Molecular Pharmacology Forum, South West University College of Pharmaceutical Sciences, Chongqing, China, July 25, 2018.

193. **Meibohm, B**: 'Exposure-Response Analysis: A Valuable Tool in Oncology Drug Development', Invited lecture, Bristol-Myers Squibb China Clinical Development, Shanghai, China, July 30, 2018.

194. **Meibohm, B:** 'The Role of Pharmacokinetic/Pharmacodynamic Evaluations in the Preclinical Development of Spectinamides, a Novel Class of Anti-Tuberculosis Agents, Keynote presentation, Annual Meeting 2018 of the German Pharmaceutical Society (DPhG), Hamburg, Germany, October 3, 2018.

195. **Meibohm, B**. Panelist: Use of Innovative Analytical Tools and Study Designs for Efficient and Feasible Pediatric Drug Development, BIO Innovation in Pediatric Drug Development Meeting, Biotechnology Innovative Organization, Washington, DC, Oct 22-23, 2018.

196. **Meibohm, B**. Integrating PMx and QSP Platform for Advancement of Biologics in Special Populations', Invited symposium presentation, AAPS PharmSci360, Washington, DC, November 7, 2018.

197. **Meibohm, B**. 'Exposure-response modeling in the preclinical development of novel anti-tuberculosis agents', Invited presentation, 8th Annual Indiana Clinical and Translational Sciences Institute (CTSI) Symposium on Disease and Therapeutic Response Modeling and Simulation, Indiana University School of Medicine, Indianapolis, IN, November 13, 2018.

198. **Meibohm, B**. 'Tissue-Agnostic Therapies in Oncology', Invited presentation, 27th North German Cytotoxics Workshop (NZW), German Society for Oncology Pharmacy (DGOP), Hamburg, Germany, January 25, 2019.

199. **Meibohm, B**: 'Basic Pharmacokinetics of Proteins', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 22, 2019.

200. **Meibohm, B**: 'PKPD in Biologics Drug Development', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 22, 2019.

201. **Meibohm, B:** 'Technical and Logistic Challenges in the Detection of Immunogenicity', Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Washington, DC, March 16, 2019.

202. **Meibohm, B.:** 'Challenges in the PKPD Assessment of Therapeutic Proteins', U.S. Food and Drug Administration, Office of Clinical Pharmacology, Silver Spring, MD, March 20, 2019.

203. **Meibohm, B**.: 'LENA Research and its Academic and Societal Impact', LENA Summit Meeting, University of Düsseldorf, Düsseldorf, Germany, March 26-27, 2019.

204. **Meibohm, B**: 'Development of Inhaled Antibiotics for the Treatment of Tuberculosis', Invited presentation, 12th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Reims, France, June 29, 2019.

205. **Meibohm, B**: 'Pediatric Clinical PK of Lacosamide: Identification of Interacting Antiepileptic Drugs and Optimal Dosing Regimens', Contributed presentation, 17th International Conference in Therapeutic Drug Monitoring & Clinical Toxicology, Foz do Iguaçu, Brazil, September 25, 2019.

206. **Meibohm, B**: Panelist: I-Act for Children Workshop on Inclusion of Adolescents in Adult Clinical Trials, Institute for Advanced Clinical Trials in Children, Washington, DC, October 15, 2019.

207. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Therapeutic Proteins in Pediatrics', Invited Lecture, Pediatric Clinical Pharmacology Course, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, Live webinar, October 30, 2019.

208. **Meibohm, B**: 'Clinical Examples to Showcase the Disposition Properties of Biologics', Invited Lecture, ISSX Workshop on Disposition of Biologics, International Society for the Study of Xenobiotics, Boston, MA, December 12, 2019.

209. **Meibohm, B**. Integrating PMx and QSP Platform for Advancement of Biologics in Special Populations', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 21, 2020.

210. **Meibohm, B:** 'Technical and Logistic Challenges in the Detection of Immunogenicity', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 21, 2020.

211. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Therapeutic Proteins in Pediatrics', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, January 21, 2020.

212. **Meibohm, B**: 'Addressing Challenges to Small and Large Molecule ADME Pharmacokinetics', Invited presentation, Land O' Lakes Annual Pharmaceutical Analysis Conference, American Association of Pharmaceutical Scientists, Virtual, August 11, 2020.

213. **Meibohm, B**: 'The Pharmacology of Therapeutic Proteins (ADME) in Pediatrics', Invited presentation, Annual meeting of the American College of Clinical Pharmacology, Virtual, September 23, 2020.

214. **Meibohm, B**: 'Biologicals in Pediatrics', Invited presentation, US Food and Drug Administration & University of Maryland CERSI Workshop on Pediatric Dose Selection, Virtual, October 22, 2020.

215. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Therapeutic Proteins in Pediatrics', Invited Lecture, Pediatric Clinical Pharmacology Course, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, Live webinar, November 4, 2020.

216. **Meibohm, B:** 'Multiple Molecular Species Complicating the PKPD of NCEs and Biologics', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, March 29, 2021.

217. **Meibohm, B**: 'Bispecific Antibodies', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, Virtual, March 29, 2021.

218. **Meibohm, B**: 'Cytokinetic Models', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, Virtual, May 21, 2021.

219. **Meibohm, B**: 'Remembering Hartmut Derendorf: The North Star of Pharmacometrics', Live webinar, American Association of Pharmaceutical Scientists, Virtual, May 27, 2021.

220. **Meibohm, B**: 'Added Value of Using PD Biomarkers over Non-Discriminative Clinical Endpoints', Live Workshop on Pharmacodynamic Biomarkers for Biosimilar Development

and Approval, U.S. Food & Drug Administration and Duke-Margolis Center for Health Policy, Virtual, September 20-21, 2021.

221. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Therapeutic Proteins in Pediatrics', Invited Lecture, Pediatric Clinical Pharmacology Course, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, Live webinar, November 10, 2021.

222. **Meibohm, B**: 'Monoclonal Antibody Dosing in Pediatrics: Rational Basis and Examples', Invited Lecture, International Workshop on Monoclonal Antibodies for HIV, COVID-19 and Oncology, Virology Education, Live webinar, November 30, 2021.

223. **Meibohm, B**: 'Opportunities to Improve Dose Optimization', Invited Lecture, US Food and Drug Administration – American Society for Clinical Oncology Virtual Workshop: Getting the Dose Right: Optimizing dose Selection Strategies in Oncology, FDA-ASCO, Live webinar, May 5, 2022.

224. **Meibohm, B**: 'PKPD of New Biological Entities', Invited workshop, Merck KGaA, Live workshop, Romano Canavese, Italy, May 11-12, 2022.

225. **Meibohm, B**: 'Challenges of Model-Informed Drug Development for Monoclonal Antibodies in Children', 13th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology, Basel, Switzerland, June 4, 2022.

226. **Meibohm, B**: 'PKPD of Proteins in Pediatrics', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, July 5, 2022.

227. **Meibohm, B**: 'Major Determinants of Between-Subject Variability in PKPD of mAbs', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, July 5, 2022.

228. **Meibohm, B**: 'Tissue and Tumor Distribution of Therapeutic Proteins', Invited lecture, Institut für Pharmazie, Freie Universität Berlin, Germany, July 5, 2022.

229. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics: Principles and Pharmacometric Approaches', Training course, Boehringer Ingelheim Pharma GmbH & Co. KG, Virtual, September 28-30, 2022.

230. **Meibohm, B.** 'The Value Continuum of PKPD: From Post-Marketing to Preclinical Development', IV RedIF Iberoamerican Pharmacometrics Network, Porto Alegre, Brazil, October 7, 2022.

231. **Meibohm, B**: 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics: Principles and Pharmacometric Approaches', Training course, AstraZeneca UK Limited, Virtual, October 11-13, 2022.

232. **Meibohm, B**: 'PK/PD Challenges in the Development of Therapeutic Proteins', Virtual webinar, International Symposium on Pharmacometrics & Systems Pharmacology, Shanghai Medical Forum, Fudan University, Shanghai, China, November 7, 2022.

233. **Meibohm, B**: 'Immunogenicity in Clinical Studies', Virtual webinar, Immunogenicity Workshop Series, Genmab, Princeton, November 8, 2022.

234. **Meibohm, B**: 'BI-US Course on Pharmacokinetics and Pharmacodynamics of Protein Therapeutics: Principles and Pharmacometric Approaches', Training course, Boehringer Ingelheim US, Virtual, January 17-19, 2023.

235. **Meibohm, B**: 'Introduction to NBE PK and PK/PD Translational Concepts', Invited Pesentation, Boehringer Ingelheim US, Ridgefield, CT, January 24, 2023.

236. **Meibohm, B**: 'Perspectives on ADA Assessment and Impact on Efficacy/Safety', Invited Pesentation, Boehringer Ingelheim US, Ridgefield, CT, January 24, 2023.

237. **Meibohm, B**: 'Clinical Pharmacology Challenges & Opportunities in the Development of Protein-Based Therapeutics', Clinical Pharmacology Platform Meeting, Boehringer Ingelheim Pharma GmbH & Co. KG, Virtual, March 28, 2023.

EDITORIAL APPOINTMENTS

- **Associate Editor**
  - **The AAPS Journal**, American Association of Pharmaceutical Scientists, 2008 - present.
  - **Frontiers in Obstetric and Pediatric Pharmacology**, Frontiers/Nature Publishing, Jan 2014 – present.
- **Section Editor**
  - **Journal of Clinical Pharmacology**, Section Editor for Pharmacokinetics and Pharmacodynamics Jul 2003 – Dec 2013
- **Guest Editor**
  - **The AAPS Journal**: Themed issue on 'Quantitative Pharmacology, a Roadmap to Model-Based Drug Development'. American Association of Pharmaceutical Scientists, 2007.
  - **The AAPS Journal**: Themed issue on 'Impact of Immunogenicity on the PKPD of Protein Therapeutics'. American Association of Pharmaceutical Scientists, 2011.
  - **The AAPS Journal**: Themed issue on 'Pediatric Drug Development'. American Association of Pharmaceutical Scientists, 2012.
  - **Journal of Clinical Pharmacology** (with J Korth-Bradley, D Mager, H Zhou): Supplemental Issue "Biologics", American College of clinical Pharmacology 2015.
  - **Drug Metabolism and Disposition** (with JS Leeder): Special Issue on Pediatric Drug Disposition and Pharmacokinetics, American Society for Experimental Pharmacology and Therapeutics, 2016.
- **Editorial Board**
  - **Journal of Clinical Pharmacology**, American College of Clinical Pharmacology/Wiley, Jan 2003 – present.
  - **Journal of Pharmacokinetics and Pharmacodynamics**, Springer, New York, Jan 2009 – present.
  - **Clinical Pharmacokinetics**, Springer - Adis, Jan 2014 – present.
  - **Current Pharmacology Reports**, Springer, New York, Dec 2015 – present.

- **European Journal of Oncology Pharmacy**, Wolters Kluwer, London, UK, Jan 2017 – present.
- **Pharmaceutics,** MDPI, Basel, Switzerland, Jan 2021 – present.
- **Die Pharmazie**, Govi-Verlag, Eschborn, Germany, Jan 2004 – Dec 2019.
- **Les Annales Pharmaceutiques Françaises**, Elsevier, Paris, France, Jan 2008 - Dec 2014.
- **Journal of Pediatric Pharmacology and Therapeutics**, Pediatric Pharmacy Advocacy Group, Jun 2000 – 2022.

COMMITTEES AND OFFICES HELD

- **University of Tennessee, Memphis, TN**

  College of Pharmacy

  - Chair, Department of Pharmaceutical Sciences 2022 - present
    - Acting/Interim Chair 2021
    - Interim Chair 2015 – 2017
  - Associate Dean for Research and Graduate Programs, 2008 - present
  - Executive Committee: Ex officio Member 2012 – present
  - Budget Committee: Ex officio Member 2012 – present
  - Research Committee: Chair, 2009-2010; Ex officio Member 2010 – present
  - Graduate Education Committee: Chair, 2010 – 2012. Ex officio Member 2013 - present
  - Space committee: Ex officio Member, 2012 – present
  - Accreditation Self-Study
    - Committee on Faculty & Staff: Chair, 2007. Member 2013-2014
    - Committee on Facilities & Resources: Co-Chair, 2020 - 2022
  - Search Committee for Dean College of Pharmacy, 2021 - 2022
  - Search Committee for Assistant Dean for Finance, 2021
  - Promotion and Tenure Committee: Chair 2011 & 2015; Member 2009-2015 & 2019-2020
  - Search Committee for Pharmaceutical Sciences Faculty Positions: Member, 2000-2001, 2006, 2009, 2010, 2012-16, 2019-present; Chair 2002
  - COP Research Council: Member, 2013 - 2016
  - Assessment Committee: Member, 2001 – 2003; 2013 - 2014
  - Curriculum Committee: Member, 2001 – 2012
  - Building Committee: Subcommittee Chair, 2004 – 2011
  - Academic Planning Council: Member, 2008 – 2010

- Web & Technology Committee: Chair, 2006 - 2009
- Graduate Seminar Series: Director, 2000 – 2008
- Honors, Awards & Scholarships Committee: Member, 1999 – 2002
- Faculty Advisor for P-1 Students in the Professional Program (Pharm.D.), Fall 2001, 2002, 2003

Health Science Center Campus

- UTHSC Vice Chancellor for Research Advisory Cabinet, 2015 – present
- UTHSC Graduate Studies Council: Member, 2008 - present
- UTHSC Medicinal Chemistry Core Advisory Board, 2018 – present
- UTHSC Vice Chancellor for Research Strategic Planning Committee, 2015 – 2017 and 2020 – 2021
- UTHSC Statistics and Experimental Design Task Force, 2017 – 2018
- Search Committees
  - Director of the Regional Biocontainment Lab: Member, 2016 - 2017
  - Vice Chancellor for Research: Member, 2010-2011, 2013, 2014-2015
  - Senior Associate Vice Chancellor for Research: Member 2021-2022
- University of Tennessee Research Foundation: Advisory Board Member, 2009-2012
- UTHSC Research Council: Member, 2010 – 2012
- Information Technology / CIO Advisory Committee: Member, 2006 – 2010
- Web Page Task Force: Member, 2006 – 2007

- **University of South Carolina, College of Pharmacy, Columbia, SC**
  - Scholastic Standing, Petitions and Admissions Committee: Member, 1998 – 1999
  - Animal Care Committee: Member, 1998 – 1999
  - Search Committee for Pharmacy Practice Faculty Position: Member, 1998
  - Search Committee for Clinical Pharmacy Faculty Positions: Member, 1999
  - Faculty Advisor for Pharmacy Students in the Professional Program (Pharm.D.): 1998 & 1999
  - Faculty Advisor for the American Pharmaceutical Association - Academy of Students of Pharmacy (APhA-ASP): 1999

- **National Institutes of Health**
  - NIH Special Emphasis Panel ZAR1 AAA-C O2 – Office of Women's Health Research (OWHR): Ad hoc member, 2002
  - NIH Special Emphasis Panel ZDK1 GRB-7 O3 - National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK): Ad hoc member, 2004

- NIH Special Emphasis Panel ZRG HOP-U 40 R – Office of Women's Health Research (OWHR): Ad hoc member, 2007
- NIH Special Emphasis Panel/Scientific Review Group ZRG1 BST-K (52) R: Ad hoc member, 2010
- NIH Special Emphasis Panel/Scientific Review Group ZRG1 IDM S (02): Ad hoc member, 2011
- NIH Special Emphasis Panel/Scientific Review Group ZEB1 OSR-C M2 P: Ad hoc member, February 2013
- NIH Special Emphasis Panel/Scientific Review Group ZAI1-FDS-M-J2: Ad hoc member, January 2014
- NIH Special Emphasis Panel ZHD1 DSR-Z (50) – Eunice Kennedy Shriver National Institute of Child Health and Human Development: Ad hoc member, July 2016
- NIH Special Emphasis Panel/Scientific Review Group ZRG1 ETTN-M/C/D (50): **Chairperson**: June 2014, February 2015, November 2015, March 2019 Member: June 2012, October 2012, February 2014, November 2015, November 2017
- NIH Special Emphasis Panel/Scientific Review Group ZRG1 IDM-W (50): Ad hoc member, November 2019
- NIH Special Emphasis Panel/Scientific Review Group CRFS: Ad hoc member, October 2018
- NIH Special Emphasis Panel/Scientific Review Group ZRG1 ETTN-C/P/M (11): Member: June 2011, November 2011, March 2012, June 2012, October 2012, March 2013, June 2013, February 2014, October 2014, February 2015, November 2015, March 2016, November 2016, March 2017, November 2017, November 2018, November 2019, March 2022, June 2022
- NIH Lung Injury, Repair, and Remodeling (LIRR) Study Section: Ad hoc member, October 2020
- NIH Special Emphasis Panel ZTR1 NTU-7 (01), NCATS: Ad hoc member, May 2021
- NIH Special Emphasis Panel ZAI1 CD-A (C1), NIAID: Ad hoc member, May 2021
- NIH DDR Study Section: Ad hoc member, July 2021
- NIH Special Emphasis Panel ZTR1 RD-7 (01), NCATS: Ad hoc member, September 2021

- **Food and Drug Administration**
  - Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology, Center for Drug Evaluation and Research, FDA: Special Government Employee, 2010 - 2011; 2014 - 2015

- **Professional Organizations**
  - **American Association of Pharmaceutical Scientists (AAPS)**

- Executive Council/Board of Directors
  - Member-at-large 2016 - 2019
- Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM) Section (~3,600 members), 1995 - 2017
  - Vice Chair 2008
  - Chair-Elect 2009
  - Chair 2010
  - Past Chair 2011
- Modeling and Simulation Focus Group, 2003 - 2014
  - Chair-Elect 2004 - 2005
  - Chair 2006 - 2007
  - Past Chair 2008 - 2009
- Southern Regional Discussion Group, 2001 - 2014
  - Vice Chair 2003
  - Chair 2004
- AAPS Education Task Force
  - Member 2010 - 2011
- AAPS Awards Task Force
  - Member 2011 - 2012
- AAPS Task Force on Research Funding
  - Member 2013 - 2014
- AAPS Nominations Committee
  - Member 2021 - 2022
- AAPS Task Force to Combine Annual Meeting with the National Biotechnology Conference
  - Member 2015 - 2017
- AAPS book publishing advisory board
  - Advisory board member 2010 - 2021
- University of Tennessee Student Chapter of the American Association of Pharmaceutical Scientists
  - Faculty Advisor, 2003 - 2011
- Annual Meeting Abstract Screening
  - Topic Chair - Population PK/PD 2003, 2004, 2005, 2006
- Meeting Event Organizer/Moderator
  - AAPS Short Course: *'Modeling & Simulation 101'*, AAPS Annual Meeting 2005, Nashville, TN
  - AAPS/ACCP Joint Symposium: *'Quantitative Pharmacology: An Overarching Theme in Critical Path Drug Development'*, AAPS Annual Meeting 2006, San Antonio, TX

- AAPS Workshop: *'Quantitative Pharmacology: A Roadmap to Model-Based Drug Development'*, AAPS Annual Meeting 2007, Pre-meeting workshop, San Diego, CA
- AAPS Roundtable: *'Pathophysiological Meets Modeling; Disease Progression Models'*, AAPS Annual Meeting 2007, San Diego, CA
- AAPS Workshop: *'Translational Biomarkers for Accelerating Drug Development: from Preclinical to Clinical'*, Baltimore, MD, May 6-7, 2009
- AAPS Workshop: *'A QMBDD workshop on Pharmacokinetic/-Pharmacodynamic Modeling in Drug Discovery and Translational Research'*, Pre-meeting workshop, Los Angeles, CA, Nov 7, 2009
- AAPS/ACCP Joint Symposium: *'Strategic Biomarkers for Treating Diseases in Younger Children Safely and Effectively'*, AAPS Annual Meeting, Los Angeles, CA, Nov 9, 2009
- AAPS Sunrise Session: *'Today, Tomorrow and Beyond: Approaches and Challenges in Modeling PD Effects with Long Time Delays'*, AAPS Annual Meeting, Los Angeles, CA, Nov 11, 2009
- AAPS Biotechnology 101: *Fundamentals of Biotherapeutics Development, eLearning series*, Team/steering committee member, 2011
- AAPS Short Course: *Translational Challenges in Developing Antibody-Drug Conjugates*, AAPS National Biotechnology Conference, May 24, 2012, San Diego, CA
- AAPS Roundtable Session: *Small Molecule Plasma and Tissue Protein Binding: Set it Free*, AAPS Annual Meeting, Chicago, IL, Oct 10, 2012

- **American College of Clinical Pharmacology (ACCP)**
  - Honorary Regent 2019 - present (for life)
  - Immediate Past President 2016 - 2018
  - President 2014 - 2016
  - President-Elect 2012 - 2014
  - Board of Regents (governing body)
    - Elected Regent 2008 - 2013
  - Awards Committee
    - Member 2019 – present
  - Annual Meeting Planning Committee
    - Member 2019 – 2021
  - Publications Committee
    - Chair 2010 - 2014
  - e-Education Committee
    - Chair 2005 - 2009
  - ACCP Symposium: Biosimilars: An Evolving Science, ACCP Annual Meeting, San Diego, CA, September 19, 2017

- **International Society on Pharmacometrics (ISoP)**
  - Elected member of the Board of Directors, 2022 – Present
  - ACCP/ISoP Special Interest Group on Clinical Pharmacometrics
    - ACCP Board liaison 2020 – 2021
  - Meeting Event Organizer/Moderator
    - Session: *Where Will The Pharmacometricians Of The Future Come From?*, American Conference on Pharmacometrics, Mashantucket, CT, October 4-7, 2009
    - Session: *Advances in Pediatric Physiologically Based Pharmacokinetic Modeling in Pediatric Drug Development*, American Conference on Pharmacometrics, Ft. Lauderdale, FL, May 13, 2013

- **Other Organizations**
  - NONMEM Testing Consortium, 2002
  - German Research Foundation (DFG), Bonn, Germany: Ad hoc reviewer 2007, 2010
  - Medical Research Council (MRC), Swindon, UK: Ad hoc reviewer 2016, 2018
  - Chairperson for Plenary Session/European Society of Oncology Pharmacy sessions at the 7th, 8th, 9th, 10th, 11th, 12th, 13th, 14th, 15th, 16th, 18th, 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th North German Cytotoxics Workshop (1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2021, 2022)

- **Tenure & Promotion External Reviewer:**
  - Auburn University
  - Children's Hospital of Los Angeles
  - Duke University
  - Freie Universität Berlin (2)
  - Leiden University
  - Ohio State University
  - University at Buffalo / State University of New York (8)
  - University of Cincinnati
  - University of Florida (6)
  - University of Kansas
  - University of Mississippi
  - University of North Carolina
  - University of Nebraska (2)
  - University of Oklahoma
  - University of Pennsylvania
  - University of Utah
  - Virginia Commonwealth University

- **Scientific Journal Reviewer**
  - AAPS Journal
  - ACS Pharmacology and Translational Science
  - Anesthesiology
  - Antimicrobial Agents and Chemotherapy
  - Archives of Disease in Childhood
  - Basic & Clinical Pharmacology & Toxicology
  - Biochemical Genetics
  - Biotechniques
  - Biopharmaceutics and Drug Disposition
  - BMC Pediatrics
  - British Journal of Clinical Pharmacology
  - Clinical Cancer Research
  - Clinical Drug Investigation
  - Clinical Pharmacokinetics
  - Clinical Pharmacology and Therapeutics
  - Clinical Pharmacology in Drug Development
  - Clinical Microbiology and Infection
  - Contemporary Clinical Trial Communications
  - Controlled Clinical Trials
  - CPT: Pharmacometrics & Systems Pharmacology
  - Current Therapeutic Research
  - Drug Discovery Today
  - European Journal of Pharmaceutical Sciences
  - Expert Opinion on Drug Metabolism
  - Frontiers in Pharmacology
  - International Journal of Clinical Pharmacology and Therapeutics
  - International Journal of Impotence Research
  - Journal of Agricultural and Food Chemistry
  - Journal of Clinical Pharmacology
  - Journal of Infectious Diseases
  - Journal of Oncology Pharmacy Practice
  - Journal of Pediatric Pharmacology and Therapeutics
  - Journal of Pediatrics
  - Journal of Pharmaceutical Sciences
  - Journal of Pharmacokinetics and Pharmacodynamics
  - Journal of Pharmacology and Experimental Therapeutics
  - Journal of Pharmacy and Pharmacology
  - Journal of Thrombosis and Haemostasis
  - Methods and Findings in Experimental and Clinical Pharmacology
  - Naunyn-Schmiedeberg's Archives of Pharmacology

- Pharmaceutical Research
- Pharmacology and Therapeutics
- Pharmacology Research & Perspectives
- Pharmacogenomics
- Pharmacotherapy
- Scientific Reports
- Tuberculosis

- **Consultancy**
  - Current:
    - Allen & Overy LLP, London, UK
    - Beigene Ltd., Camana Bay, Cayman Islands
    - Boehringer Ingelheim, Biberach, Germany
    - F. Hoffmann-La Roche Ltd, Basel, Switzerland
    - Gilead Sciences, Foster City, CA
    - Servier Institut de Recherches Internationales, Paris, France
    - Tonix Pharmaceuticals, New York, NY
  - Previous
    - Abbvie, Ludwigshafen, Germany
    - Acceleron Pharma Inc, Cambridge, MA
    - Amgen Inc., Thousand Oaks, CA
    - Alexion Pharmaceuticals, New Haven, CT
    - Almac Sciences Ltd, Belfast, Northern Ireland, UK
    - Altana Pharma, Melville, NY
    - Applied BioMath, Cambridge , MA
    - AstraZeneca, Mölndal, Sweden/Waltham, MA/Alderley Park, UK
    - Bayer AG, Wuppertal, Germany
    - Biocon Research Ltd., Bangalore, India
    - Biogen Idec, Cambridge, MA
    - Bristows LLP, London, UK
    - Corrs, Chambers, Westgarth, Melbourne, Australia
    - CSL Behring, Melbourne, Australia
    - Compugen Ltd., Israel
    - Edimer Pharmaceuticals, Cambridge, MA
    - EMD Serono, Billerica, MA
    - Enobia Pharma, Montreal, Canada
    - Formycon GmbH, Martinsried, Germany
    - Genomics Institute of the Novartis Research Foundation, San Diego, CA
    - Goodwin Procter LLP, New York, NY
    - Icon Plc, Dublin, Ireland
    - Janssen Research & Development, J&J, Spring House, PA
    - KAI, Rockville, MD

- Krele Pharmaceuticals, Saddle Brook, NJ
- Latham & Watkins LLP, Washington, DC
- Lipocine Inc., Salt Lake City, UT
- MedImmune, Gaithersburg, MD
- Merck KGaA/MerckSerono, Darmstadt, Germany
- Merck Sharp & Dohme Corp., Whitehouse Station, NJ
- Millennium Pharmaceuticals, Cambridge, MA
- Molecular Partners, Zürich, Switzerland
- Novartis Pharmaceuticals Corporation, East Hanover, NJ
- Paranta Biosciences, Melbourne, Australia
- Pieris Proteolab, Freising, Germany
- Sanofi, Bridgewater, NJ
- Takeda Pharmaceuticals, Cambridge, MA
- Teva Pharmaceutical Industries Ltd, Netanya, Israel
- UCB Biopharma SPRL, Brussels, Belgium
- Vela Pharmaceuticals, Lawrenceville, NJ

OTHER PROFESSIONAL ACTIVITIES

- **Patents & Disclosures**

Non-Provisional Patent Application Docket No. D6550 / Jan 9, 2004
Real-Time Polymerase Chain Reaction-Based Genotyping Assay for Beta 2-Adrenergic Receptor Single Nucleotide Polymorphism; **Meibohm** et al., USSN 11/032,541
University of Tennessee Research Foundation Disclosure UTRF PD 03030

Non-Provisional Patent Application Docket No. D6561 / Feb 25, 2004
Real-Time Polymerase Chain Reaction-Based Genotyping Assay for Chemokine Receptor (CXCR2) Single Nucleotide Polymorphism; **Meibohm** et al., USSN 11/066,586
University of Tennessee Research Foundation Disclosure UTRF PD 03031.

Invention Disclosure, May 16, 2008
An *in vitro* PK/PD Model to Determine Time-Kill Curves of Antibiotics against Slow-Growing Microorganisms; **Meibohm, B**, Lee, RE, Lee, REB, Budha, NR.
University of Tennessee Research Foundation Disclosure UTRF PD 08088

United States Patent US 8,685,978 B2 / April 1, 2014
United States Patent Application Serial No.12/843,551 / July 26, 2010
Provisional Patent Application Serial No.61/228,266 / July 24, 2009
Foreign Patent Application P.C.T. Serial No.PCT/US10/043244 / July 26, 2010
Spectinamides as anti-tuberculosis agents; Lee RE, **Meibohm B**, Jianjun Q, Hurdle JG, Rakesh, Vaddady PK
University of Tennessee Research Foundation Disclosure UTRF PD 09085

United States Patent US 9,284,325 B2 / March 15, 2016
Division of Application No. 12/843,551 / July 26, 2010

Provisional Patent Application Serial No.61/228,266 / July 24, 2009
Spectinamides as anti-tuberculosis agents; Lee RE, **Meibohm B**, Jianjun Q, Hurdle JG, Rakesh, Vaddady PK
University of Tennessee Research Foundation Disclosure UTRF PD 09085

Invention Disclosure, November 5, 2018
Dry Powder Formulations of an Anti-Tuberculosis Drug and Methods of Treatment using the same; **Meibohm, B**, Lee, RE, Durham, PG, Gonzalez-Juarrero, M, Liu, J, Stuart, I, James, A, Lukka PB.
University of Tennessee Research Foundation Disclosure UTRF PD 19081-05

FELLOWS/GRADUATE STUDENTS TRAINED

Graduate Student Trainees:

- **University of Tennessee, College of Pharmacy, Memphis, TN**

Wenhui Zhang	Aug 1999 – Dec 2003. PhD in Pharmaceutical Sciences.
	Dissertation: 'Ontogeny of Mechanisms in Drug Disposition: Age-Dependency of P-glycoprotein Expression and Renal Elimination Exemplified by the Sotalol Pharmacokinetics'
	First professional position: Senior Research Pharmacologist, Clinical Pharmacology & Pharmacometrics, Abbott, Chicago, IL
Manish Gupta	Aug 2000 – Mar 2005. PhD in Pharmaceutical Sciences.
	Dissertation: 'Genetic and Molecular Factors in Chronic Obstructive Pulmonary Disease'
	First professional position: Senior Pharmacologist, Clinical Pharmacology, Pfizer Inc. , Ann Arbor, MI
Lisa Tang	Aug 2000 – Oct 2007. PharmD/PhD in Pharmaceutical Sciences.
	Dissertation: 'Age-Associated Hepatic Drug Transporter Expression and its Implications for Pediatric Pharmacotherapy
	First professional position: Pending
Nageshwar R. Budha	Aug 2004 – Feb 2009. PhD in Pharmaceutical sciences.
	Dissertation: 'Genetic and Molecular Factors in Chronic Obstructive Pulmonary Disease'
	First professional position: Research Scientist, Late Stage Clinical Development, Genentech, Inc, South San Francisco, CA
Nathaniel L. Dirks	Aug 2001 – Feb 2010. PharmD/PhD in Pharmaceutical Sciences.
	Dissertation: 'Population Pharmacokinetics of Therapeutic Monoclonal Antibodies: Examples and Estimation Method Performance Differences'
	First professional position: Research Scientist, Metrum Research Group, Tariffville, CT
Pavan K. Vaddady	Aug 2006 – April 2011. PhD in Pharmaceutical Sciences.
	Dissertation: 'Pharmacokinetic and Pharmacodynamic Studies of a Novel Spectinamide Series of antituberculosis Agents'
	First professional position: Senior Research Pharmacokineticist, Merck & Co, Kenilworth, NJ
Yi Zhang, MD	Aug 2006 – April 2012. PhD in Pharmaceutical Sciences.
	Dissertation: 'Investigations of Pharmacokinetic Challenges in Premature Infants'

	First professional position: Fellow, Pharmacometric group, U.S. Food and Drug Administration, Silver Spring, MD
Ashit Trivedi	Aug 2010 – Sep 2015. PhD in Pharmaceutical Sciences.
	Dissertation: 'Optimization of Lead Spectinamide Compounds as Novel Anti-Tuberculosis Agents with a Pharmacometric Approach'
	First professional position: Scientist, Amgen Inc, Thousand Oaks,CA
Wararat Limothai	Aug 2008 – Nov 2015. PhD in Pharmaceutical Sciences.
	Dissertation: 'Challenges in the Pharmacokinetics of Therapeutic Proteins'
	First professional position: Government Pharmaceutical Organization, Bangkok, Thailand
Chetan Rathi	Aug 2011 – Feb 2017. PhD in Pharmaceutical Sciences.
	Dissertation: 'Translational Pharmacokinetic-Pharmacodynamic Modeling And Simulation In The Development Of Spectinamides, A Novel Class Of Anti-tuberculosis Agents'
	First professional position: GlaxoSmithKline, King of Prussia, PA
Margaret Thompson	Jan 2004 – Mar 2017. PharmD/PhD in pharmaceutical sciences. Dissertation: 'Age-Associated Expression Patterns of OATP 1B1 and OATP 1B3 and Their Effect on the Disposition of Fexofenadine'
	First professional position: Instructor, University of Tennessee College of Pharmacy
Ryman, Josiah	Aug 2008 – Mar 2017. PharmD/PhD in pharmaceutical sciences. Dissertation: 'The Development of Methods to Account for Physiologic Dynamic Changes and Their Effects on the Pharmacokinetics of Therapeutic Monoclonal Antibodies and other Therapeutics'
	First professional position: Merck & Co., Kenilworth, NJ
Santosh J. Wagh	Aug 2015 – Sep 2020. PhD student in pharmaceutical sciences.
	Dissertation: 'Model Based Dose-Exposure-Response Assessment for Lead and Backup Spectinamide in a Mouse Model of Tuberculosis'
	First professional position: Pfizer Inc., Cambridge, MA
Keyur Parmar	Aug 2017 – Jan 2023. PhD student in pharmaceutical sciences.
	Dissertation: 'Physiologically Based Pharmacokinetic (PBPK) Modeling for the Preclinical Development of Spectinamide Antibiotics'
	First professional position: Merck & Co, Rahway, NJ
Zaid Temrikar	Aug 2017— Dec 2022. PhD student in pharmaceutical sciences.

	Dissertation: 'PKPD-Model Based Preclinical Characterization of the Activity of Spectinamide 1599 against Mycobacterial Subpopulations and the Identification of Potential Partners for Combination Therapy'
	First professional position: Gilead Sciences, Foster City, CA
Paridhi Gupta	Aug 2019—present. PhD student in pharmaceutical sciences.
Hyunseo Park	Dec 2020—present. PhD student in pharmaceutical sciences.
Bhargavi Thalluri	Aug 2021—present. PhD student in pharmaceutical sciences.
Christelle Mathieu	Aug 2022-present. PharmD/PhD student.

- **University of South Carolina, College of Pharmacy**

Wenhui Zhang	Jan 1999 – Aug 1999. PhD student in pharmaceutics. Transferred to University of Tennessee.
Andrew G. Larkin	Sep 1998 – May 2002. MS in Pharmaceutical Sciences.
	Thesis: 'Comparability of Parameter Estimates by Different Pharmacokinetic/Pharmacodynamic Software'
	First professional position: Research Associate, St. Jude Children's Research Hospital, Memphis, TN

<u>Postdoctoral Trainees:</u>

- **University of Tennessee, College of Pharmacy, Memphis, TN**

Nitin Mehrotra, PhD	Central Drug Research Inst., Lucknow, India	2005-2007
	First professional position: Office of Clinical Pharmacology, U.S. Food and Drug Administration, Silver Spring, MD	
Satyendra Suryawanshi, PhD	Central Drug Research Inst., Lucknow, India	2008-2010
	First professional position: Clinical Pharmacology, Bristol Myers Squibb, Princeton, NJ	
Lei Diao, PhD	University of Maryland, Baltimore, MD	2011-2012
	First professional position: Pharmacometrics, Biogen-Idec, Boston, MA	
Dora Madhura, PhD	University of North Carolina, Chapel Hill, NC	2010-2015
	First professional position: Drug discovery, Genomics Institute of the Novartis Research Foundation, San Diego, CA	
Sumit Rawal, PhD	University of North Carolina, Chapel Hill, NC	2012-2014
	First professional position: Clinical Pharmacology and Pharmacometrics, Regeneron Pharmaceuticals, Tarrytown, NY	

Pradeep B. Lukka, PhD	University of California San Francisco, CA	2015-2020
	First professional position: Senior Manager, AstraZeneca, Gaithersburg, MD	
Ashish Srivastava, PhD	Central Drug Research Institute, Lucknow, India	2020-present
Amarinder Singh, PhD	Syngene International, Bangalore, India	2022-present

Undergraduate Student Trainees:

- **University of Tennessee, College of Pharmacy, Memphis, TN**

Charles Thompson	University of Tennessee	2000
Amber Williams	Tennessee Tech University	2006
Gillian Bell	University of Tennessee	2008

Visiting Scientists & Postgraduate Trainees:

- **University of Tennessee, College of Pharmacy, Memphis, TN**

Markus Fluck, PhD	Merck KGaA, Munich, Germany	2001
Birte Huth, BS	University of Heidelberg, Germany	2001
Ashish Sharma, PhD	Laval University, Ste-Foy, Canada	2001
Brigitte Brockhaus, MS	Merck KGaA, Darmstadt, Germany	2002
Katrin Thomas, BS	University of Kiel, Germany	2003
Stephanie Läer, MD, PhD	University of Hamburg, Germany	2003-2004
Stephanie Röhm, PhD	Heinrich-Heine-Univ., Düsseldorf, Germany	2008
Sophie Krauel, BS	Martin-Luther University, Halle, Germany	2011
Karolin Kromke, BS	Martin Luther University, Halle, Germany	2011
Simone Kasek, BS	Technical University Braunschweig, Germany	2012
Lucas Praetorius, BS	Free University Berlin, Germany	2014
Tobias Härsjö, MS	University of Gothenburg, Sweden	2014
Dorina Van der Mey, PhD	Bayer Healthcare, Germany	2015-2016
Doreen Kruse, BS	Free University Berlin, Germany	2017-2018

- **University of South Carolina, College of Pharmacy**

Stephanie Läer, MD, PhD	University of Hamburg, Germany	1999
Frederike Behn, PhD	University of Hamburg, Germany	1999

Graduate Student Dissertation Committees:

- **University of Tennessee Health Science Center, Memphis, TN**

Donghua Yin, PhD	(Major Advisor: J.T. Dalton, PhD)	1999
Yichun Sun, PhD	(Major Advisor: A.J. Shukla, PhD)	2000
Chris Watts, PhD	(Major Advisor: A.J. Shukla, PhD)	2000-2002
N. Aksornkoae, PhD	(Major Advisor: A.J. Shukla, PhD)	2000-2002
Yanli Mi, PhD	(Major Advisor: G.C. Wood, PhD)	2000-2002
Mathew Edick, PhD	(Major Advisor: M.V. Relling, PharmD)	2000-2003

Wenhui Zhang, PhD	(Major Advisor: B. Meibohm, PhD)	2000-2003
Manish Gupta, PhD	(Major Advisor: B. Meibohm, PhD)	2002-2005
Costellia A. Talley, PhD	(Major Advisor: M.N. Wicks, PhD)	2002-2005
Miguel DeFina, DDS, MS	(Major Advisor: J.A. Katancik, PhD)	2003-2005
Shen Li, PhD	(Major Advisor: C.R. Yates, PharmD, PhD)	2002-2005
Pengfei Song, PhD	(Major Advisor: C.R. Yates, PharmD, PhD)	2002-2005
Bo Jiang, PhD	(Major Advisor: A.J. Shukla, PhD)	2003-2006
Quanmin Chen, PhD	(Major Advisor: A.J. Shukla, PhD)	2003-2006
Yanli Zhuang, PhD	(Major Advisor: C.F. Steward, PharmD)	2004-2006
Kun Chen, PhD	(Major Advisor: R.I. Mahato, PhD)	2004-2007
Gerald Rajan, PhD	(Major Advisor: A.J. Shukla, PhD)	2004-2007
Kelli Turner, PharmD, PhD	(Major Advisor: C.F. Stewart, PharmD)	2004-2007
Lei Yang, PhD	(Major Advisor: M.V. Relling, PharmD)	2004-2007
Lisa Tang, PharmD, PhD	(Major Advisor: B. Meibohm, PhD)	2004-2007
Vishal Lamba, PhD	(Major Advisor: E.G. Schuetz, PhD)	2003-2008
Teresa Liu, PhD	(Major Advisor: P.D. Rogers, PharmD, PhD)	2003-2008
Om Anand, PhD	(Major Advisor: A.J. Shukla, PhD)	2006-2008
Jun Chen, PhD	(Major Advisor: C.F. Steward, PharmD)	2006-2008
Kelli Filipski, PhD	(Major Advisor: A. Sparreboom, PhD)	2007-2008
Nageshwar Budha, PhD	Major Advisor: B. Meibohm, PhD)	2006-2009
Leslie B. Stuart, PharmD	(Major Advisor: C.R. Yates, PharmD, PhD)	2006-2009
Nathanael L. Dirks, PharmD, PhD	(Major Advisor: B. Meibohm, PhD)	2006-2010
Zhao Wang, PhD	(Major Advisor: W. Li, PhD)	2007-2010
Kui Zeng, PhD	(Major Advisor: D.D. Miller, PhD)	2007-2010
Kelly Caudle, PharmD, PhD	(Major Advisor: P.D. Rogers, PharmD,PhD)	2008-2010
Sonia Bedi, PhD	(Major Advisor: A.J. Shukla, PhD)	2008-2011
Pavan Vaddady, PhD	(Major Advisor: B. Meibohm, PhD)	2008-2011
Lin Zhu, PhD	(Major Advisor: R.I. Mahato, PhD)	2008-2011
Karin Emmons, PhD	(Major Advisor: C.R. Yates, PharmD, PhD)	2007-2011
Fan Zhang, PhD	(Major Advisor: C.F. Stewart, PharmD)	2009-2011
Fei Ma, PhD	(Major Advisor: C.R. Yates, PharmD, PhD)	2007-2012
Yi Zhang, MD, PhD	(Major Advisor: B. Meibohm, PhD)	2008-2012
Hao Wu, PhD	(Major Advisor: R.I. Mahato, PhD)	2010-2013
Stephanie Flowers, PhD	(Major Advisor: P.D. Rogers, PharmD, PhD)	2011-2013
Sibo Jiang, PhD	(Major Advisor: T. Lowe, MS)	2013
Elizabeth Griffith, PhD	(Major Advisor: Richard Lee, PhD)	2011-2015
Ashit Trivedi, PhD	(Major Advisor: B. Meibohm, PhD)	2013-2015
Wararat Limothai, PhD	(Major Advisor: B. Meibohm, PhD)	2009-2015
Elizabeth Berkow, PhD	(Major Advisor: P.D. Rogers, PharmD, PhD)	2012-2015
Jin Wang, PhD	(Major Advisor: W Li, PhD)	2013-2015
Jordan Toutounchian, PhD	(Major Advisor: C.R. Yates, PharmD, PhD)	2013-2016
Chetan Rathi, PhD	(Major Advisor: B. Meibohm, PhD)	2013-2016
Dileep R. Janagam, PhD	(Major Advisor: T. Lowe, PhD)	2014-2016
Shajila Siricilla, PhD	(Major Advisor: M. Kurosu, PhD)	2014-2017
Margaret Thomson, PharmD, PhD	(Major Advisor: B. Meibohm, PhD)	2008-2017
Josiah Ryman, PharmD, PhD	(Major Advisor: B. Meibohm, PhD)	2013-2017

Sri Chandana, MS	(Major Advisor: T. Lowe, MS)	2017
Sarah Whaley, PharmD, PhD	(Major Advisor: P. David Rogers, PharmD, PhD)	2012-2017
Samit Ganguly, PhD	(Major Advisor: E.G. Schuetz, PhD)	2013-2018
M. Arifur Rahman, PhD	(Major Advisor: S Kumar, PhD)	2015-2019
Doaa N. A. Maria, PhD	(Major Advisor: M. Jablonski, PhD)	2016-2018
Kinsie Arnst, PhD	(Major Advisor: W. Li, PhD)	2016-2018
Alex Mugengana, PhD	(Major Advisor: R.E. Lee, PhD)	2016-2019
Sangyoon Kim, MS	(Major Advisor: T. Lowe, PhD)	2019
Pallabita Chowdhury PhD	(Major Advisor: S. Kumar, PhD)	2017-2019
Santosh J. Wagh, PhD	(Major Advisor: B. Meibohm, PhD)	2016-2020
Shaki Eslamimehr, MS	(Major Advisor: M. Kurosu, PhD)	2018-2020
Nicole Vita	(Major Advisor: R.E. Lee, PhD)	2018-2022
Fatemeh Keramatnia	(Major Advisor: M. Fischer, PhD)	2019-2022
Zaid Temrikar	(Major Advisor: B. Meibohm, PhD)	2019-2022
Keyur Parmar	(Major Advisor: B. Meibohm, PhD)	2019-2023
Najah Albadari	(Major Advisor: W. Li, PhD)	2020-present
Faiza Tahia	(Major Advisor: N. Mandal, PhD)	2020-present
Rui Wang	(Major Advisor: W. Li, PhD)	2020-present
Gupta, Paridhi	(Major Advisor: B. Meibohm, PhD)	2020-present
Hyunseo Park	(Major Advisor: B. Meibohm, PhD)	2021-present
Lina Zhou	(Major Advisor: S. Kumar, PhD)	2021-present
Bhargavi Thalluri	(Major Advisor: B. Meibohm, PhD)	2021-present
Mingle, David	(Major Advisor: M. Kurosu, PhD)	2021-present
Hartman, Kelli	(Major Advisor: W. Li, PhD)	2022-present
Jenner, Alexander	(Major Advisor: R.E. Lee, PhD)	2023-present

- **University of South Carolina, College of Pharmacy, Columbia, SC**

Charles S. Asbill, PhD	(Major Advisor: B.B. Michniak, PhD)	1998-1999
Ayman El-Kattan, PhD	(Major Advisor: B.B. Michniak, PhD)	1998-1999

- **Medical University of South Carolina, College of Pharmacy, Charleston, SC**

Josephine Fubara, PhD	(Major Advisor: R. Notari, PhD)	1998

<u>Honors and Awards Received by Supervised Graduate Students/Trainees:</u>

Charles Thompson

- Summer fellowship grant by American Heart Association through the UT Center of Excellence for Vascular Biology. – 2000

Wenhui Zhang

- Globomax Foundation – Workshop Grant Award – 2003

Manish Gupta

- American Association of Pharmaceutical Sciences (AAPS) – Clinical Sciences Section – Annual Meeting Travel Award – 2003

- AAPS Southern Regional Discussion Group – PharmForum 2004 – Outstanding Podium Presentation
- American College of Clinical Pharmacology (ACCP) - Student / Trainee Award - 2004

Lisa Tang, PharmD

- American Foundation for Pharmaceutical Education (AFPE) - Rho Chi Schering-Plough Graduate Scholarship – 2003
- American College of Clinical Pharmacology (ACCP) - Student / Trainee Award – 2004
- American Foundation for Pharmaceutical Education (AFPE) – Predoctoral Fellowship – 2004 & 2005
- Wayne A. Colburn Memorial Award for Best Trainee Poster Presentation at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), September 2004
- Presidential Trainee Award for Poster/Podium Presentation at the 106th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), March 2005
- Invitation for the 3rd Summer Institute in Maternal-Fetal Pharmacology organized by the National Institute of Child Health & Human Development (NICHD) and Canada's CIHR's Institute of Human Development, Child and Youth Health (IHDCYH)
- PPDM/CPTR Graduate Symposium Award at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Nov 2007

Nathanael L. Dirks, PharmD

- American Foundation for Pharmaceutical Education (AFPE) – Predoctoral Fellowship – 2006 & 2007
- 2007 AAPS-AFPE Pre-Doctoral Fellowship in Pharmaceutical Sciences

Nageshwar R. Budha

- Finalist Podium Presentation Award, South East Regional Interdisciplinary Symposium (SERIS) – University of Florida, Gainesville, FL, May 19-21, 2006.
- American Association of Pharmaceutical Sciences (AAPS) – CPTR Section – Annual Meeting Travel Award – 2007

Margaret M. Thomson, PharmD

- University of Tennessee National Alumni Association Joe & Pat Johnson Scholarship - 2007.
- American Association of Pharmaceutical Sciences (AAPS) – CPTR Section – Annual Meeting Travel Award – 2007
- American Foundation for Pharmaceutical Education (AFPE) – Predoctoral Fellowship – 2008, 2009, 2010

- AAPS Southern Regional Discussion Group – PharmForum 2008 – Outstanding Podium Presentation
- AAPS Southern Regional Discussion Group – PharmForum 2013 – Outstanding Podium Presentation
- American Association of Pharmaceutical Sciences (AAPS) – CPTR Section – Annual Meeting Travel Award – 2013

Nitin Mehrotra, PhD

- American College of Clinical Pharmacology (ACCP) - Trainee Award – 2007

Yi Zhang, MD

- American Association of Pharmaceutical Sciences (AAPS) – CPTR Section – Annual Meeting Travel Award – 2007

Pavan K Vaddady

- AAPS Southern Regional Discussion Group - PharmForum 2009 - Outstanding Podium Presentation
- PPDM/CPTR Graduate Symposium Award at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Nov 2010

Satyendra Suryawanshi, PhD

- American College of Clinical Pharmacology (ACCP) - Trainee Award – 2009

Wararat Limothai

- American Association of Pharmaceutical Sciences (AAPS) – PPDM Section – Annual Meeting Travel Award – 2011

Josiah Ryman, PharmD

- AAPS Southern Regional Discussion Group – PharmForum 2013 – Outstanding Poster Presentation
- American College of Clinical Pharmacology (ACCP) – Trainee Award 2013
- American Association of Pharmaceutical Sciences (AAPS) – PPDM Section – Annual Meeting Travel Award – 2013

Ashit Trivedi

- College of Graduate Health Sciences travel award 2013
- AAPS Southern Regional Discussion Group – PharmForum 2013 – Poster presentation Honorable Mention
- American Society of Microbiology – Student and Postdoctoral Fellow Travel Grant for ICAAC 2013
- PPDM/CPTR Graduate Student Research Award at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Nov 2014

Chetan Rathi

- American Society of Microbiology ICAAC travel grant 2013

- UTHSC College of Graduate Health Sciences – Graduate Research Day 2014: 3rd year Poster Presentation Winner
- College of Graduate Health Sciences Travel Award 2015
- 6th American Conference on Pharmacometrics Travel Award 2015
- Team Winner – Merck Serono Innovation Cup Summer Camp, Frankfurt, Germany 2016
- Invitee – New York Academy of Sciences/PepsiCo Journey through Science Day, World Trade Center, New York City, NY, 2016

Zaid Temrikar

- College of Graduate Health Sciences Travel Award 2019
- 2nd Place for Research Presentation – Graduate Research Day - College of Graduate Health Sciences 2021
- American College of Clinical Pharmacology – ACCP Leadership Development Program 2021
- American College of Clinical Pharmacology – New Member Recognition 2021
- Winner - Graduate Student Executive Council and the UTHSC College of Graduate Health Sciences Three minute Thesis competition Oct 2021

Keyur Parmar

- College of Graduate Health Sciences Travel Award 2019
- American Society for Clinical Pharmacology and Therapeutics (ASCPT) – Presidential Training Award - 2022

Pradeep B Lukka, PhD

- American College of Clinical Pharmacology (ACCP) - Trainee Award – 2019
- Wayne A. Colburn Memorial Award for Best Trainee Poster Presentation at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), September 2019

Ashish Srivastava, PhD

- Co-President – UTHSC Postdoc Association – 2021-2022

PUBLICATIONS

METRICS

- ✓ **PUBMED: 163 ARTICLES**

  https://www.ncbi.nlm.nih.gov/sites/myncbi/1Xsir8mOSga/bibliography/49096288/public/?sort=date&direction=descending

- ✓ **GOOGLE SCHOLAR: 12,018 citations; *h*-INDEX 53; *i10* -INDEX 126**

- ✓ **SCOPUS: 189 ARTICLES, 8,642 citations; *h*-INDEX 47**

The * symbol in the following list indicates the role of a first, corresponding or senior author in the respective publication.

BOOKS

1. Meibohm, B (Ed). Pharmacokinetics and Pharmacodynamics of Biotech Drugs: Principles and Case Studies in Drug Development. Wiley-VCH, Weinheim 2006, ISBN 978-3527314089.*
2. Crommelin, DJA, Sindelar, RD, Meibohm, B (Eds). Pharmaceutical Biotechnology: Fundamentals and Applications, 3rd Edition, Informa Healthcare, New York 2007, ISBN 1-420-04437-0.*
3. Zhou, H, Meibohm, B (Eds). Drug-Drug Interactions for Therapeutic Biologics, 1st Edition, Wiley, Hoboken 2013, ISBN 978-1118032169.*
4. Crommelin, DJA, Sindelar, RD, Meibohm, B (Eds). Pharmaceutical Biotechnology: Fundamentals and Applications, 4th Edition, Springer, New York 2013, ISBN 978-1118032169.*
5. Crommelin, DJA, Sindelar, RD, Meibohm, B (Eds). Pharmaceutical Biotechnology: Fundamentals and Applications, 5th Edition, Springer, New York 2019, ISBN 978-3030007096.*

BOOK CHAPTERS

6. **Meibohm, B**: Antiarrhythmics (in German). In: ADKA-Committee for Clinical Pharmacy (Eds.): Praxis of Clinical Pharmacy. Vol. I: Clinical Pharmacokinetics. Deutscher Apotheker Verlag, Stuttgart 1992, ISBN 3-7692-1478-1, p. 128-150.*
7. **Meibohm, B**, Derendorf H: Pharmacokinetics and Pharmacodynamics of Biotechnology Drugs (in German). In: Müller, RH, Kayser, O (Eds.): Pharmazeutische Biotechnologie. WVG Wissenschaftliche Verlagsgesellschaft, Stuttgart 2000, ISBN 3-8047-1768-3, p. 103-124.*
8. **Meibohm, B**: Coronary Heart Disease. In: Schneemann, H (Ed.): Handbook of Applied Pharmacotherapy, Springer, Berlin 2001, ISBN 3-540-41356-1, p. 169-191.*

9. **Meibohm, B**: Peripheral Vascular Disease. In: Schneemann, H (Ed.): Handbook of Applied Pharmacotherapy, Springer, Berlin 2001, ISBN 3-540-41356-1, p. 193-205.*
10. **Meibohm, B**: Theophylline. In: Schoenwald, RD (Ed.): Pharmacokinetics in Drug Discovery and Development, CRC Press, Boca Raton 2002, ISBN 1-56676-973-6, p. 201-229.*
11. **Meibohm, B**, Derendorf H: Pharmacokinetics and Pharmacodynamics of Biotechnology Drugs (in Polish). In: Müller, RH, Kayser, O (Eds.): Biotechnologia Farmaceutyczna, Wydawnictwo Lekarskie PZWL, Warszawa 2003, ISBN 83-200-2751-9, p. 91-110.*
12. Yates, CR**, Meibohm, B**. Pharmacokinetics. In: Gourley, DR, Eoff, JC (Eds.): APhA's Complete Review for Pharmacy, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th ed., American Pharmacists Association, 2004-2013, ISBN 978-1-58212-176-5, p. 161-186.*
13. **Meibohm, B**, Derendorf H: Pharmacokinetics and Pharmacodynamics of Biotech Drugs. In: Kayser, O, Müller, RH (Eds.): Pharmaceutical Biotechnology, Wiley-VCH, Weinheim 2004, ISBN 3-527-30554-8, p. 147-172.*
14. Kovar, A, **Meibohm, B**. Drug Development in Oncology. In: Bonate, P, Howard, D (Eds.): Pharmacokinetics in Drug Development: An Industrial Perspective, AAPS Press, Alexandria, VA 2004, ISBN 0-9711767-3-6, p. 281-303.*
15. **Meibohm, B**: Pharmacokinetics of Protein- and Nucleotide-Based Drugs. In: Mahato, RI (Ed.): Biomaterials-Based Delivery and Biocompatibility of Proteins and Nucleic Acids, CRC Press, Boca Raton, FL 2005, ISBN 0-8493-2334-7, p. 275-294.*
16. **Meibohm, B**, Derendorf H: Pharmacokinetics and Pharmacodynamics of Biotech Drugs. In: Meyers, RA (Ed.): Encyclopedia of Molecular Cell Biology and Molecular Medicine, 2nd Edition. Volume 10, Wiley-VCH, Weinheim 2005, ISBN 3-527-30552-1, p. 211-241.*
17. **Meibohm, B**, Evans, WE: Clinical Pharmacodynamics & Pharmacokinetics. In: Helms, RA, Quan, DJ: Textbook of Therapeutics: Drug and Disease Management, 8th Ed., Lippincott Williams Wilkins 2006, ISBN 0-7817-5734, p. 1-31.*
18. **Meibohm, B**: The Role of Pharmacokinetics of Peptides and Proteins. In: Meibohm, B (Ed). Pharmacokinetics and Pharmacodynamics and Pharmacodynamics in the Development of Biotech Drugs. Wiley-VCH, Weinheim 2006, ISBN 3-527-31408-3, p. 3-13.*
19. Tang, L, **Meibohm, B**: Pharmacokinetics of Peptides and Proteins. In: Meibohm, B (Ed). Pharmacokinetics and Pharmacodynamics of Biotech Drugs. Wiley-VCH, Weinheim 2006, ISBN 3-527-31408-3, p. 17-43.*
20. **Meibohm, B**, Braeckman, R. Pharmacokinetics and Pharmacodynamics of Peptides and Proteins. In: Crommelin, DJA, Sindelar, RD, **Meibohm, B** (Eds). Pharmaceutical Biotechnology: Concepts and Applications, 3rd Edition, Informa Healthcare, New York 2007, ISBN 1-420-04437-0, p. 95-123.*
21. Vaddady, PK, **Meibohm, B**. Biopharmaceutics, Pharmacokinetics and Pharmacodynamics of Protein Therapeutics. In: Flickinger, MC. Encyclopedia of Industrial Biotechnology. Wiley-VCH, Weinheim 2010.*

22. **Meibohm, B**. Pharmacology. In: Gourley, DR. The APhA Complete Review for the Foreign Pharmacy Equivalency Examination. American Pharmacists Association, Washington DC 2011, ISBN 1-582-12143-5.*

23. Laer, S, **Meibohm, B**. Study Design and Simulation Approach. In: Seyberth, HW, Schwab, M. (eds.), Pediatric Clinical Pharmacology, Handbook of Experimental Pharmacology 205, p. 125-148. Springer, Berlin 2011 DOI 10.1007/978-3-642-20195-0_6.*

24. Zhang, Y, **Meibohm, B**. Pharmacokinetics and Exposure-Response Relationships of Biotech Drugs and Biosimilars. In: Xie, H, Huang, X, Shi, J. Quantitative Pharmacology and Drug Development. People's Military Medical Press. Beijing, China 2011.*

25. **Meibohm, B**. Pharmacokinetics and Half-Life of Protein Therapeutics. In: Kontermann, R: Therapeutics Proteins: Strategies to Modulate Their Plasma Half-Lives, Wiley-Blackwell 2012, ISBN 978-3-527-32849-9, p. 23-38.*

26. Zhang, Y, **Meibohm, B**, Pharmacokinetics and Pharmacodynamics of Therapeutic Peptides and Proteins. In: Kayser, O, Warzecha, H: Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications, Wiley-VCH, Weinheim 2012, ISBN 978-3-527-32994-6, p. 337-367.*

27. **Meibohm, B**, Zhou, H. Drug interactions for therapeutic proteins: a journey just starts …In: Zhou, H, Meibohm, B (Eds). Drug-Drug Interactions for Therapeutic Biologics, 1st Edition, Wiley, Hoboken 2013, ISBN 978-1118032169.*

28. Leu, J, Kasek, S, Li, C, Limothai, W, Madhura, D, Rathi, C, Rawal, S, Ryman, J, Thomson, M, Trivedi, A, Zhou, H, **Meibohm, B**. Monographs for Drug-Drug Interactions of Therapeutic Biologics. In: Zhou, H, Meibohm, B (Eds). Drug-Drug Interactions for Therapeutic Biologics, 1st Edition, Wiley, Hoboken 2013, ISBN 978-1118032169, p. 275-349.*

29. **Meibohm, B**, Braeckman, R. Pharmacokinetics and Pharmacodynamics of Peptides and Proteins. In: Crommelin, DJA, Sindelar, RD, **Meibohm, B** (Eds). Pharmaceutical Biotechnology: Concepts and Applications. 4th Edition, Springer, New York 2013, ISBN 978-1118032169, p. 101-132.*

30. **Meibohm, B,** Yates, CR. Pharmacokinetics, Drug Metabolism and Drug Disposition. In: Chyka, PA, Boucher, BA, Franks, AS, Waddell, JA (Eds.): APhA's Complete Review for Pharmacy, 11th Edition, American Pharmacists Association, 2015, ISBN 978-1-58212-217-5, p. 111-135.*

31. Rathi, C**, Meibohm, B**: Pharmacokinetics of Peptides and Proteins. In: Meyers, RA (Ed.): Reviews in Cell Biology and Molecular Medicine, 3rd ed., Wiley, Weinheim 2015, ISBN 9783527600908, p. 300-26.*

32. Rathi, C**, Meibohm, B**: ADME for Therapeutic Biologics: Antibody-Derived Proteins and Proteins with Novel Scaffolds. In: Zhou, H, Theil, FP. ADME and Translational Pharmacokinetics/Pharmacodynamics of Therapeutic Proteins. Wiley, Hoboken 2016, ISBN 978-1-118-89864-2.*

33. **Meibohm, B,** Yates, CR. Pharmacokinetics, Drug Metabolism and Drug Disposition. In: Chyka, PA, Franks, AS, Waddell, JA, Boucher, BA (Eds.): The APhA Complete Review for Pharmacy, 12th ed., American Pharmacists Association, Washington, DC, 2017, ISBN 9781582122816, p. 123-150.*

34. **Meibohm, B**. Pharmacology. In: Boucher BA (Ed). The APhA Complete Review for the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), 2nd Edition. American Pharmacists Association, Washington 2018, ISBN 978-1-58212-298-4, p. 111-128.*

35. **Meibohm, B**. Pharmacokinetics and Pharmacodynamics of Peptides and Proteins. In: Crommelin, DJA, Sindelar, RD, **Meibohm, B** (Eds). Pharmaceutical Biotechnology: Concepts and Applications. 5th Edition, Springer, New York 2019, ISBN 978-3030007096, p. 105-137.*

36. Lukka PB, Wagh S, **Meibohm B.** Translational Considerations in Developing Bispecific Antibodies: What Can We Learn from Quantitative Pharmacology? In: Mould D, Zhou, H (Eds.). Quantitative Pharmacology and Individualized Therapy Strategies in Development of Therapeutic Proteins for Immune-Mediated Inflammatory Diseases, Wiley, Hoboken, 2019, ISBN 978-1119289197, p. 187-208.*

37. **Meibohm, B**. Pharmacology. Boucher BA (Ed). The Complete PCOA Review. American Pharmacists Association, Washington DC, 2020, ISBN 978-1582123417. p. 111-128.*

38. Temrikar ZH, Suryawanshi S, **Meibohm B**. Chapter 44: Monoclonal Antibodies. In: Aranda JV, van den Anker JN. Yaffe and Aranda's Neonatal and Pediatric Pharmacology: Therapeutic Principles in Practice. 5th ed., Wolters Kluver, 2020, ISBN 978-1975112486/978-1975112509.*

39. Meduri GU, Confalonieri M, Chaudhuri D, Rochwerg B, **Meibohm B**. Chapter 24: Prolonged glucocorticoid treatment in ARDS: Pathobiological rationale and pharmacological principles. In: Fink G (Ed). Stress: Immunology and Inflammation, Handbook of Stress Series Volume 5, 1st ed., Elsevier, Amsterdam, 2023, ISBN 978-0128175583.

SCIENTIFIC JOURNAL ARTICLES

40. **Meibohm, B**, Wegener, S: Mexiletine-theophylline-interaction. Krankenhauspharmazie 13(7) (1992), 331-333.*

41. Steffens, KJ, Schreiber, R, **Meibohm, B**: TPN-regimes and parenteral fat emulsions. Krankenhauspharmazie 13(9) (1992), 426-430.

42. Rohatagi, S, Bye, A, Falcoz, C, Mackie, AE, **Meibohm, B**, Möllmann, H, Derendorf, H: Dynamic modeling of cortisol reduction after inhaled administration of fluticasone propionate. Journal of Clinical Pharmacology 36 (1996), 938-941.

43. **Meibohm, B**, Hochhaus, G, Rohatagi, S, Möllmann, H, Barth, J, Wagner, M, Krieg, M, Stöckmann, R, Derendorf, H: Dependency of cortisol suppression on the administration time of inhaled corticosteroids. Journal of Clinical Pharmacology 37 (1997), 704-710.*

44. **Meibohm, B**, Derendorf, H: Basic concepts of pharmacokinetic/pharmacodynamic (PK/PD) modeling. International Journal of Clinical Pharmacology and Therapeutics 35 (1997), 401-413.*

45. Derendorf, H, Möllmann, H, Hochhaus, G, **Meibohm, B**, Barth, J: Clinical PK/PD-modeling as a tool in drug development of corticosteroids. International Journal of Clinical Pharmacology and Therapeutics 35 (1997), 481-488.

46. Möllmann, H, Derendorf, H, Barth, J, **Meibohm, B**, Wagner, M, Krieg, M, Köller, J, Hochhaus, G: Pharmacokinetic/pharmacodynamic evaluation of the systemic effects of flunisolide after inhalation. Journal of Clinical Pharmacology 37 (1997), 893-903.

47. **Meibohm, B**, Garms, T, Meier, K, Melzer, S, Schwarz, S: Pharmacoeconomic benefit of a patient oriented automated drug distribution system combined with intensive advisory services. Journal of Applied Therapeutics 1 (1997), 343-349.*

48. Möllmann, H, Wagner, M, **Meibohm, B**, Hochhaus, G, Barth, J, Stöckmann, R, Krieg, M, Weisser, H, Falcoz, C, Derendorf, H: Pharmacokinetic and pharmacodynamic evaluation of fluticasone propionate after inhaled administration. European Journal of Clinical Pharmacology 53 (1998), 459-467.

49. Derendorf, H, Hochhaus, G, **Meibohm, B**, Möllmann, H, Barth, J. Pharmacokinetics and pharmacodynamics of inhaled corticosteroids. Journal of Allergy and Clinical Immunology 101 (1998), S440-S446.

50. **Meibohm, B**, Möllmann, H, Wagner, M, Hochhaus, G, Möllmann, A, Derendorf, H: The clinical pharmacology of fluticasone propionate. Reviews in Contemporary Pharmacotherapy 9 (1998), 535-549.*

51. Derendorf, H, **Meibohm, B**: Modeling of pharmacokinetic/pharmacodynamic (PK/PD) relationships: Concepts and perspectives. Pharmaceutical Research 16 (1999), 176-185.

52. **Meibohm, B**, Derendorf, H, Möllmann, H, Fröehlich, P, Tromm, A, Wagner, M, , Homrighausen, S, Krieg, M, Hochhaus, G: Mechanism-based PK/PD model for the lymphocytopenia induced by endogenous and exogenous corticosteroids. International Journal of Clinical Pharmacology and Therapeutics 37 (1999), 367-376.*

53. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Wagner, M, Krieg, M, Stöckmann, R, Derendorf, H: A PK/PD-approach to predict the cumulative cortisol suppression of inhaled corticosteroids. Journal of Pharmacokinetics and Biopharmaceutics 27 (1999), 127-147.*

54. Beierle, I, **Meibohm, B**, Derendorf, H: Gender differences in pharmacokinetics and pharmacodynamics. International Journal of Clinical Pharmacology and Therapeutics 37 (1999), 529-547.

55. Derendorf, H, Hochhaus, G, Krishnaswami, S, **Meibohm, B**, Möllmann, H. Optimized therapeutic ratio of inhaled corticosteroids using retrometabolism. Pharmazie 55 (2000), 223-227.

56. **Meibohm, B**, Zhang, W, Beierle, I, Meyer, MC. Epistaxis associated with elevation of INR in a patient switched to generic warfarin – another view. Pharmacotherapy 20 (2000), 866-871.*

57. Läer, S, Wauer, I, Behn, F, Scholz, H, Mir, TS, Weil, J, **Meibohm, B**, Hulpke-Wette, M. Pharmacokinetics of sotalol in different age groups of children with tachycardia. Journal of Pediatric Pharmacology and Therapeutics 6 (2001), 50-59.

58. Läer, S, **Meibohm, B,** Mir, TS, Hulpke-Wette, M. Termination of automatic atrial tachycardia in an infant by adequate sotalol dosing: Indication of clinically relevant age-

dependent pharmacokinetics of sotalol. European Journal of Clinical Pharmacology 57 (2001), 181-182.

59. **Meibohm, B**, Derendorf, H. Pharmacokinetic/pharmacodynamic studies in drug product development. Journal of Pharmaceutical Sciences 91 (2002), 18-31.*
60. **Meibohm, B,** Beierle, I, Derendorf, H: How important are gender differences in pharmacokinetics ? Clinical Pharmacokinetics 41 (2002), 329-342.*
61. Läer, S, Behn, F, Scholz, H, Mir, TS, Eiselt, M, Venske, A, **Meibohm, B**, Weil, J. ß-Receptor Carvedilol therapy in patients with congestive heart failure: A study investigating clinical and pharmacokinetic parameters. American Heart Journal 143 (2002), 916-922.
62. Song P, Li S, **Meibohm B**, Gaber AO, Honaker MR, Kotb M, and Yates CR. Detection of MDR1 single nucleotide polymorphisms (SNPs) C3435T and G2677T using real-time PCR. AAPS PharmSci 4 (2002), article 29.
63. Yates, CR, Zhang, W, Song, P, Gaber, AO, Kotb, M, Honaker, MR, Alloway, RR**, Meibohm, B**. The effect of CYP3A5 and MDR1 polymorphic expression on cyclosporine oral disposition in renal transplant patients. Journal of Clinical Pharmacology 43 (2003), 555-564.*
64. Gupta, M, Song, P, Yates, CR, **Meibohm, B**. A real-time PCR genotyping assay for CXCR2 polymorphisms. Clinica Chimica Acta 341(2004), 93-100.*
65. Tang, L, Persky, AM, Hochhaus, G, **Meibohm, B**. Pharmacokinetic Aspects of Biotechnology Products. Journal of Pharmaceutical Sciences 93 (2004), 2184-2204.*
66. Dirks, NL, Huth, B, Yates, CR, **Meibohm, B**. Pharmacokinetics of Immunosuppressants: A Perspective on Ethnic Differences. International Journal of Clinical Pharmacology and Therapeutics 42 (2004), 701-718.*
67. Sharma, A, Pibarot, P, Pilote, S, Dumesnil, JG, Arsenault, M, Bélanger, PM, **Meibohm, B**, Hamelin, BA. Modulation of metoprolol pharmacokinetics and hemodynamics by diphenhydramine coadministration during exercise testing in healthy premenopausal women. Journal of Pharmacology and Experimental Therapeutics 313 (2005), 1172-81.
68. Song, P, **Meibohm, B**, Yates, CR. LC/MS/MS in Drug Development: Targeting the Brain. Biotechniques 38 (2005), S19-S23
69. Gupta, M, Kovar, A, **Meibohm, B**. The Clinical Pharmacokinetics of Phosphodiesterase-5 Inhibitors for Erectile Dysfunction. Journal of Clinical Pharmacology 45 (2005), 987-1003.*
70. Gupta, M, Yates, CR, **Meibohm, B**. SYBR Green-Based Real-Time PCR Allelic Discrimination Assay for β2-Adrenergic Receptor Polymorphisms. Analytical Biochemistry 344 (2005), 292-294.*
71. Christensen, ML, **Meibohm, B**, Capparelli, EV, Velasquez-Meyer, P, Burghen, GA, Tamborlane, WV. Single and multiple dose pharmacokinetics of pioglitazone in adolescents with type 2 diabetes. Journal of Clinical Pharmacology 45 (2005), 1137-1144.
72. **Meibohm, B**, Läer, S, Panetta, JC, Barrett, JS. Population Pharmacokinetic Studies in Pediatrics: Issues in Design and Analysis. AAPS Journal 7 (2005), Article 48, E475-487.*

73. Läer, S, Elshoff, JP, **Meibohm, B**, Weil, J, Mir, TS, Zhang, W, Hulpke-Wette, M. Development of a Safe and Effective Pediatric Dosing Regimen for Sotalol based on Population Pharmacokinetics and Pharmacodynamics in Children with Supraventricular Tachycardia. Journal of the American College of Cardiology 46 (2005), 1322-1330.

74. Song, P, Lamba, JK, Zhang, L. Schuetz, EG, Shukla, N, **Meibohm, B**, Yates, CR. G2677T and G3435T Genotype and Haplotype are Associated with Hepatic ABCB1 (MDR1) Expression. Journal of Clinical Pharmacology 46 (2006), 373-379.

75. Chen, ML, Straughn, AB, Sadrieh, N, Meyer, M, Faustino, PJ, Ciavarrella, AB, **Meibohm, B**, Yates, CR, Hussain, AS. The Effect of Sorbitol on Bioavailability and Bioequivalence: Implication with Common Excipients. Pharmaceutical Research 2007, 24, 73-80.

76. Mehrotra, N, Gupta, M, Kovar, A, **Meibohm, B**. The Role of Pharmacokinetics and Pharmacodynamics in Phosphodiesterase-5 Inhibitor Therapy. International Journal of Impotence Research 2007, 19, 253-64.*

77. **Meibohm, B**. Pharmacokinetic and Pharmacodynamic Evaluation of Biologics: Challenges and Pitfalls. Chinese Journal of Clinical Pharmacology and Therapeutics 12 (2007), 1089-97.*

78. Tangallapally, RP, Sun, D, Rakesh R, Budha, N, Lee, REB, Lenaerts, AJ, **Meibohm, B**, Lee, RE. Discovery of Novel Isoxazolines as Anti-tuberculosis Agents. Bioorganic and Medicinal Chemistry Letters 17 (2007), 6638-42.

79. Albers, S, **Meibohm, B**, Mir, TS, Laer, S. Population pharmacokinetics and dose simulation of carvedilol in paediatric patients with congestive heart failure. British Journal of Clinical Pharmacology 2008, 65, 511-22.

80. Dirks, NL, Nolting, A, Kovar, A, **Meibohm, B**. Population Pharmacokinetics of Cetuximab in Patients with Squamous Cell Carcinoma of the Head and Neck. Journal of Clinical Pharmacology 2008, 48, 267-78.*

81. Budha, NR, Lee, RE, **Meibohm, B**. Biopharmaceutics, Pharmacokinetics and Pharmacodynamics of Antituberculosis Drugs. Current Medicinal Chemistry 2008, 15, 809-25. *

82. Budha, NR, Mehrotra, N, Tangallapally, R, Rakesh, Qi, J, Daniels, AJ, Lee, RE, **Meibohm, B**. Pharmacokinetically-Guided Lead Optimization of Nitrofuranylamide Anti-Tuberculosis Agents. AAPS Journal 2008, 10, 57-65.*

83. Hurdle, JG, Lee, RB, Budha, NR, Carson, EI, Qi, J, Scherman, MS, Wan, B, McNeil, MR, Lenaerts, AJ, Franzblau, SG, **Meibohm, B**, Lee, RE. A Microbiological Assessment of Novel Nitrofuranylamides as Anti-tuberculosis Agents. Journal of Antimicrobial Chemotherapy 2008, 62, 1037-45.

84. Mertens-Talcott, SU, Rios, J, Jilma-Stohlawetz, P, Pacheco-Palencia, LA, **Meibohm, B**, Talcott, ST, Derendorf H. Pharmacokinetics of Anthocyanins and Antioxidant Effects after the Consumption of Anthocyanin-rich Acai Juice and Pulp (Euterpe oleracea Mart.) in Human Healthy Volunteers. Journal of Agricultural and Food Chemistry 2008, 56, 7796-802.

85. Zhang, Y, Mehrotra, N, Budha, NR, Christensen, ML, **Meibohm, B**. A Tandem Mass Spectrometry Assay for the Simultaneous Determination of Acetaminophen, Caffeine, Phenytoin, Ranitidine, and Theophylline in Small Volume Pediatric Plasma Specimens. Clinica Chimica Acta 2008, 398, 105-12.*

86. Zhang, L, Pfister, M, **Meibohm, B**. Concepts and Challenges in Quantitative Pharmacology and Model-Based Drug Development. AAPS Journal 2008, 10, 552-9.*

87. Dirks, NL, Li, S, Huth, B, Hochhaus, G, Yates, CR, **Meibohm, B**. Transrepression and Transactivation Potencies of Inhaled Glucocorticoids. Pharmazie 2008, 63, 893-8.*

88. Laer, S, Barrett, JS, **Meibohm, B**. The In Silico Child: Using Simulation to Guide Pediatric Drug Development and Manage Pediatric Pharmacotherapy. Journal of Clinical Pharmacology 2009, 48, 889-904.*

89. Budha, NR, Lee, RB, Hurdle, JG, Lee, RE, **Meibohm, B**. A Simple in vitro PK/PD Model System to Determine Time-Kill Curves of Drugs against Mycobacteria. Tuberculosis 2009, 89, 378-85.*

90. Sharma, A, Pibarot, P, Pilote, S, Dumesnil, JG, Arsenault, M, Bélanger, PM, **Meibohm, B**, Hamelin, BA. Towards Optimal Treatment of Women: the Effect of Sex on Metoprolol-Diphenhydramine Interaction. Journal of Clinical Pharmacology 2010, 50, 214-225.

91. Mehrotra, N, Tolley, EA, Bauer, DC, Harris, TB, Newman, AB, Kritchevsky, SB, **Meibohm, B**. Predictors of Mortality in Elderly Subjects with Obstructive Airway. Annals of Epidemiology 2010, 20, 223-32.*

92. Kumar, R, Seibold, MA, Aldrich, MC, Williams, LK, Reiner, AP, Colangelo, L, Galanter, J, Gignoux, C, Hu, D, Sen, S, Choudhry, S, Peterson, EL, Rodriguez-Santana, J, Rodriguez-Cintron, W, Nalls, MA, Leak, TS, O'Meara, E, **Meibohm, B**, Kritchevsky, SB, Li, R, Harris, TB, Nickerson, DA, Fornage, M, Enright, P, Ziv, E, Smith, LJ, Liu, K, Burchard, EG. Genetic ancestry in lung-function predictions. New England Journal of Medicine 2010, 363(4), 321-30.

93. Dirks, NL, **Meibohm, B**. Population Pharmacokinetics of Therapeutic Monoclonal Antibodies. Clinical Pharmacokinetics 2010, 49, 633-59.*

94. Chen J, Wang Z, Li CM, Lu Y, Vaddady PK, **Meibohm B**, Dalton JT, Miller DD, Li W. Discovery of Novel 2-Aryl-4-benzoyl-imidazoles targeting the colchicines binding site in tubulin as potential anticancer agents. Journal of Medicinal Chemistry 2010, 53, 7414-27.

95. Romero, K, Corrigan, B, Tornoe, CW, Gobburu, JV, Danhof, M, Gillespie, WR, Gastonguay, MR, **Meibohm, B**, Derendorf, H. Pharmacometrics as a Discipline is Entering the 'Industrialization' Phase: Standards, Automation, Knowledge Sharing and Training are Critical for Future Success. Journal of Clinical Pharmacology 2010, 50, 9S-19S.

96. Suryawanshi, S, Zhang, L, Pfister, M, **Meibohm, B**. The current role of model-based drug development. Expert Opinion on Drug Discovery 2010, 5, 311-21.*

97. Vaddady, P, Mehrotra, N, Zhang, X, Yates, CR, Moore, BM, **Meibohm, B**. Pharmacokinetics of a Novel Combination of Δ^9-Tetrahydrocannabinol and Celecoxib in a

Porcine Model of Hemorrhagic Shock. Biopharmaceutics and Drug Disposition 2011, 32, 88-98.*

98. Vaddady, PK, Lee, RE, **Meibohm, B**. In Vitro Pharmacokinetic/Pharmacodynamic Models in Anti-infective Drug Development: Focus on Tuberculosis. Future Medicinal Chemistry 2010, 2, 1355-69.*

99. Bai, PF, Bell, R, Burckart, GJ, Buckman, S, Eichler, HG, Fang, KC, Goodsaid, FM, Jusko, WJ, Lesko, LL, **Meibohm, B**, Patterson, SD, Puig, O, Smerage, JB, Snider, BJ, Wagner, JA, Wang, J, Walton, M, Weiner, R. Translational Biomarkers: from Preclinical to Clinical. A Report of 2009 AAPS/ACCP Biomarker Workshop. AAPS Journal 2011, 13, 274-83

100. van den Borst B, Koster A, Yu B, Gosker HR, **Meibohm B**, Bauer DC, Kritchevsky SB, Liu Y, Newman AB, Harris TB, Schols AM; For the Health ABC Study. Is age-related decline in lean mass and physical function accelerated by obstructive lung disease or smoking? Thorax 2011, 66, 961-9.

101. Artigas MS, Loth DW, Wain LV, Gharib SA, Obeidat M, Tang W, Zhai G, Zhao JH, Smith AV, Huffman JE, Albrecht E, Jackson CM, Evans DM, Cadby G, Fornage M, Manichaikul A, Lopez LM, Johnson T, Aldrich MC, Aspelund T, Barroso I, Campbell H, Cassano PA, Couper DJ, Eiriksdottir G, Franceschini N, Garcia M, Gieger C, Gislason GK, Grkovic I, Hammond CJ, Hancock DB, Harris TB, Ramasamy A, Heckbert SR, Heliövaara M, Homuth G, Hysi PG, James AL, Jankovic S, Joubert BR, Karrasch S, Klopp N, Koch B, Kritchevsky SB, Launer LJ, Liu Y, Loehr LR, Lohman K, Loos RJ, Lumley T, Al Balushi KA, Ang WQ, Barr RG, Beilby J, Blakey JD, Boban M, Boraska V, Brisman J, Britton JR, Brusselle GG, Cooper C, Curjuric I, Dahgam S, Deary IJ, Ebrahim S, Eijgelsheim M, Francks C, Gaysina D, Granell R, Gu X, Hankinson JL, Hardy R, Harris SE, Henderson J, Henry A, Hingorani AD, Hofman A, Holt PG, Hui J, Hunter ML, Imboden M, Jameson KA, Kerr SM, Kolcic I, Kronenberg F, Liu JZ, Marchini J, McKeever T, Morris AD, Olin AC, Porteous DJ, Postma DS, Rich SS, Ring SM, Rivadeneira F, Rochat T, Sayer AA, Sayers I, Sly PD, Smith GD, Sood A, Starr JM, Uitterlinden AG, Vonk JM, Wannamethee SG, Whincup PH, Wijmenga C, Williams OD, Wong A, Mangino M, Marciante KD, McArdle WL, **Meibohm B**, Morrison AC, North KE, Omenaas E, Palmer LJ, Pietiläinen KH, Pin I, Pola Sbreve Ek O, Pouta A, Psaty BM, Hartikainen AL, Rantanen T, Ripatti S, Rotter JI, Rudan I, Rudnicka AR, Schulz H, Shin SY, Spector TD, Surakka I, Vitart V, Völzke H, Wareham NJ, Warrington NM, Wichmann HE, Wild SH, Wilk JB, Wjst M, Wright AF, Zgaga L, Zemunik T, Pennell CE, Nyberg F, Kuh D, Holloway JW, Boezen HM, Lawlor DA, Morris RW, Probst-Hensch N; The International Lung Cancer Consortium; GIANT consortium, Kaprio J, Wilson JF, Hayward C, Kähönen M, Heinrich J, Musk AW, Jarvis DL, Gläser S, Järvelin MR, Ch Stricker BH, Elliott P, O'Connor GT, Strachan DP, London SJ, Hall IP, Gudnason V, Tobin MD. Genome-wide association and large-scale follow up identifies 16 new loci influencing lung function. Nature Genetics 2011 Sep 25. doi: 10.1038/ng.941.

102. Prado, ME, Ryman, JT, Boileau, MJ, Martin-Jimenez, T, **Meibohm, B**. Pharmacokinetics of Oral Ponazuril in Healthy Llamas (Lama glama). American Journal of Veterinary Research 2011, 72, 1386-9.*

103. Budha NR, Kovar A, **Meibohm B**. Comparative Performance of Cell Life Span and Cell Transit Models for Describing Erythropoietic Drug Effects. AAPS Journal 2011, 13, 650-61.*

104. **Meibohm, B**. Population Pharmacokinetic/Pharmacodynamic Analyses as the Basis for Dosing of Therapeutic Monoclonal Antibodies. Clinical Pharmacokinetics 2011, 50, 823-4.*

105. **Meibohm, B**, Zhou, H. Characterizing the Impact of Renal Impairment on the Clinical Pharmacology of Biologics. Journal of Clinical Pharmacology 2012, 52 (suppl), 54S-62S.*

106. Bentley, AR, Kritchevsky, SB, Harris, TB, Newman, AB, Bauer, DC, **Meibohm, B**, Clark, AG, Cassano PA; for the Health, Aging, Body Composition Study. Genetic variation in antioxidant enzymes and lung function. Free Radical Biology and Medicine 2012, 52, 1577-83.

107. Chirmule, N, Jawa, V, **Meibohm, B**. Immunogenicity to therapeutic proteins: Impact on PK/PD and efficacy. AAPS Journal 2012, 14, 296-302. *

108. Mehrota, N, Tang, L, Phelps, S, **Meibohm, B**. Evaluation of Vancomycin Dosing Regimens in Preterm and Term Neonates using Monte-Carlo Simulations. Pharmacotherapy 2012, 32, 408-19.*

109. Kelmer, G, Bell, GC, Martin-Jimenez, T, Saxton, AM, Catasus, C, Elliot, SB, **Meibohm, B**. Evaluation of Regional Limb Perfusion with Amikacin Using the Saphenous, Cephalic and Palmar Digital Veins in Standing Horses. Journal of Veterinary Pharmacology and Therapeutics 2013, 36(3):236-40.*

110. Barrett, JS, Della Casa Alberighi, O, Laer, S, **Meibohm, B**. Physiologically-Based Pharmacokinetic (PBPK) Modeling in Children. Clinical Pharmacology and Therapeutics 2012, 92, 40-9.*

111. Aldrich, MC, Kumar, R, Colangelo, LA, Williams, LK, Sen, S, Kritchevsky, SB, **Meibohm, B**, Galanter, J, Hu, D, Gignoux, CR, Liu, Y, Harris, TB, Ziv, E, Zmuda, J, Garcia, M, Leak, TS, Foreman, MG, Smith, LJ, Fornage, M, Liu, K, Burchard, EG; for the Health ABC and CARDIA Studies. Genetic Ancestry-Smoking Interactions and Lung Function in African Americans: A Cohort Study. PLoS One 2012, 7(6), e39541.

112. van den Borst, B, Gosker, HR, Koster, A, Yu, B, Kritchevsky, SB, Liu, Y, **Meibohm, B**, Rice, TB, Shlipak, M, Yende, S, Harris, TB, Schols, AM; for the Health Aging, and Body Composition (Health ABC) Study. The influence of abdominal visceral fat on inflammatory pathways and mortality risk in obstructive lung disease. American Journal of Clinical Nutrition 2012, 96(3):516-26.

113. Wilk JB, Shrine NR, Loehr LR, Zhao JH, Manichaikul A, Lopez LM, Smith AV, Heckbert SR, Smolonska J, Tang W, Loth DW, Curjuric I, Hui J, Cho MH, Latourelle JC, Henry AP, Aldrich M, Bakke P, Beaty TH, Bentley AR, Borecki IB, Brusselle GG, Burkart KM, Chen TH, Couper D, Crapo JD, Davies G, Dupuis J, Franceschini N, Gulsvik A, Hancock DB, Harris TB, Hofman A, Imboden M, James AL, Khaw KT, Lahousse L, Launer LJ, Litonjua A, Liu Y, Lohman KK, Lomas DA, Lumley T, Marciante KD, McArdle WL, **Meibohm B**, Morrison AC, Musk AW, Myers RH, North KE, Postma DS, Psaty BM, Rich SS, Rivadeneira F, Rochat T,

Rotter JI, Soler Artigas M, Starr JM, Uitterlinden AG, Wareham NJ, Wijmenga C, Zanen P, Province MA, Silverman EK, Deary IJ, Palmer LJ, Cassano PA, Gudnason V, Barr RG, Loos RJ, Strachan DP, London SJ, Boezen HM, Probst-Hensch N, Gharib SA, Hall IP, O'Connor GT, Tobin MD, Stricker BH. Genome Wide Association Studies Identify CHRNA5/3 and HTR4 in the Development of Airflow Obstruction. American Journal of Respiratory and Critical Care Medicine 2012, 186, 622-632.

114. **Meibohm, B**, Phelps, SJ, Mehrotra, N, Tang, L. Authors' reply on Creatinine-Based Vancomycin Dosing Regimens in Neonates: There Is More to Consider Than the Variation in Drug Assay. Pharmacotherapy 2012, 32, e175.*

115. Lee, DSH, DeRekeniere, N, Hanlon, JT, Gill, TM, Bauer, DC, **Meibohm, B**, Harris, TB, Jeffrey, SM. Cognitive Impairment and Medication Complexity in Community-Living Older Adults: The Health, Aging and Body Composition Study. Journal of Pharmacy Technology 2012, 28, 156-62.

116. Swanson, JM, Wood, GC, Xu, L, Tang, LE, **Meibohm, B**, Homayouni, R, Croce MA, Fabian, TC. Developing a Gene Expression Model for Predicting Ventilator-Associated Pneumonia in Trauma Patients: A Pilot Study. PLoS ONE 2012, 7, e42065.

117. Rakesh, Bruhn D, Madhura DB, Maddox M, Lee RB, Trivedi A, Yang L, Scherman MS, Gilliland JC, Gruppo V, McNeil MR, Lenaerts AJ, **Meibohm B**, Lee RE. Antitubercular nitrofuran isoxazolines with improved pharmacokinetic properties. Bioorganic and Medicinal Chemistry 2012, 20, 6063-72.

118. Hu, ZY, Laizure, SC, **Meibohm, B**, Herring, VL, Parker RB. Simple and sensitive assay for quantification of oseltamivir and its active metabolite oseltamivir carboxylate in human plasma using high-performance liquid chromatography coupled with electrospray ionization tandem mass spectrometry: improved applicability to pharmacokinetic study. Journal of Pharmaceutical and Biomedical Analysis 2013, 72, 245-50.

119. Hancock DB, Soler Artigas M, Gharib SA, Henry A, Manichaikul A, Ramasamy A, Loth DW, Imboden M, Koch B, McArdle WL, Smith AV, Smolonska J, Sood A, Tang W, Wilk JB, Zhai G, Zhao JH, Aschard H, Burkart KM, Curjuric I, Eijgelsheim M, Elliott P, Gu X, Harris TB, Janson C, Homuth G, Hysi PG, Liu JZ, Loehr LR, Lohman K, Loos RJF, Manning AK, Marciante KD, Obeidat M, Postma DS, Aldrich MC, Brusselle GG, Chen T-H, Eiriksdottir G, Franceschini N, Heinrich J, Rotter JI, Wijmenga C, Williams OD, Bentley AR, Hofman A, Laurie CC, Lumley T, Morrison AC, Joubert BR, Rivadeneira F, Couper DJ, Kritchevsky SB, Liu Y, Wjst M, Wain LV, Vonk JM, Uitterlinden AG, Rochat T, Rich SS, Psaty BM, O'Connor GT, North KE, Mirel DB, **Meibohm B**, Launer LJ, Khaw K-T, Hartikainen A-L, Hammond CJ, Gläser S, Marchini J, Kraft P, Wareham NJ, Völzke H, Stricker BHC, Spector TD, Probst-Hensch NM, Jarvis D, Jarvelin M-R, Heckbert SR, Gudnason V, Boezen HM, Barr RG, Cassano PA†, Strachan DP†, Fornage M†, Hall IP†, Dupuis J†, Tobin MD†, and London SJ† (2012). Genome-wide joint meta-analysis of SNP and SNP-by-smoking interaction identifies novel loci for pulmonary function. PLoS Genetics, 2012, 8(12), e1003098.

120. Della Casa Alberighi O, Barrett JS, Läer S, **Meibohm B**. Response to "Physiologically Based Pharmacokinetic Modeling at the Extremes of Age". Clinical Pharmacology and Therapeutics 2013,93(2), 149.*

121. Thudium K, Bilic S, Leipold D, Mallet W, Kaur S, **Meibohm B**, Erickson H, Tibbitts J, Zhao H, Gupta M. American Association of Pharmaceutical Scientists National Biotechnology Conference Short Course: Translational Challenges in Developing Antibody-Drug Conjugates: May 24, 2012, San Diego, CA. MAbs. 2013, 5(1), 5-12.

122. Bai JP, Barrett JS, Burckart GJ, **Meibohm B**, Sachs HC, Yao L. Strategic Biomarkers for Drug Development in Treating Rare Diseases and Diseases in Neonates and Infants. AAPS Journal 2013, 15, 447-54.

123. Trivedi, A, Lee, RE, **Meibohm, B**. Application of Pharmacometric in the Clinical Development and Pharmacotherapy of Anti-Infectives. Expert Review of Clinical Pharmacology 2013, 6, 159-70.*

124. Tang W, Bentley AR, Kritchevsky SB, Harris, TB, Newman AB, Bauer DC, **Meibohm B**, Cassano PA. Genetic Variation in Antioxidant Enzymes, Cigarette Smoking and Longitudinal Change in Lung Function. Free Radical Biology and Medicine 2013, 63, 204-12.

125. Diao, L, **Meibohm, B**. Pharmacokinetics and Pharmacokinetic-Pharmacodynamic Correlations of Therapeutic Peptides. Clinical Pharmacokinetics 2013, 52, 855-68.*

126. Madhura, DB, Lee, RE, **Meibohm, B**. Pharmacokinetic Profile of Spectinomycin in Rats. Pharmazie 2013, 68, 675-6.*

127. Ramusovic S, Läer S, **Meibohm B**, Lagler FB, Paul T. Pharmacokinetics of Intravenous Amiodarone in Children. Archives of Disease in Childhood 2013, 98, 989-93.*

128. Swaminathan S, Li H, Palamoor M, de Obarrio WT, Madhura D, **Meibohm B**, Jablonski MM. Novel Endogenous Glycan Therapy for Retinal Diseases: Safety, In Vitro Stability, Ocular Pharmacokinetic Modeling, and Biodistribution. AAPS Journal 2014, 16, 311-23.

129. Lee RE, Hurdle JG, Liu J, Bruhn DF, Matt T, Scherman MS, Vaddady PK, Zheng Z, Qi J, Akbergenov R, Das S, Madhura DB, Rathi C, Trivedi A, Villellas C, Lee RB, Rakesh, Waidyarachchi SL, Sun D, McNeil MR, Ainsa JA, Boshoff HI, Gonzalez-Juarrero M, **Meibohm B**, Böttger EC, Lenaerts AJ. Spectinamides: a new class of semisynthetic antituberculosis agents that overcome native drug efflux. Nature Medicine 2014, 20(2), 152-8. doi: 10.1038/nm.3458.*

130. Rakesh, Bruhn DF, Scherman MS, Woolhiser LK, Madhura DB, Maddox MM, Singh AP, Lee RB, Hurdle JG, McNeil MR, Lenaerts AJ, **Meibohm B**, Lee RE. Pentacyclic Nitrofurans with In Vivo Efficacy and Activity against Nonreplicating Mycobacterium tuberculosis. PLoS One 2014, 9, e87909.

131. W Tang, M Kowgier, DW Loth, M Soler Artigas, BR Joubert, E Hodge, SA Gharib, AV Smith, I Ruczinski, V Gudnason, RA Mathias, TB Harris, NN Hansel, LJ Launer, KC Barnes, JG Hansen, E Albrecht, MC Aldrich, M Allerhand, RG Barr, GG Brusselle, DJ Couper, I Curjuric, G Davies, IJ Deary, J Dupuis, T Fall, M Foy, N Franceschini, W Gao, S Gläser, X Gu, DB Hancock, J Heinrich, A Hofman, M Imboden, E Ingelsson, A James, S Karrasch, B Koch, SB Kritchevsky, A Kumar, L Lahousse, G Li, L Lind, C Lindgren, Y Liu, K Lohman, T Lumley, WL McArdle, **B Meibohm**, AP Morris, AC Morrison, B Musk, KE North, LJ Palmer, NM Probst-Hensch, BM Psaty, F Rivadeneira, JI Rotter, H Schulz, LJ Smith, A Sood, JM

Starr, DP Strachan, A Teumer, AG Uitterlinden, H Völzke, A Voorman, LV Wain, MT Wells, JB Wilk, OD Williams, SR Heckbert, BH Stricker, SJ London, M Fornage, MD Tobin, GT O'Connor, IP Hall, PA Cassano (2014). Large-scale Genome-Wide Association Studies and Meta-analyses of Longitudinal Change in Adult Lung Function. PLoS One 2014, 9(7), e100776. doi: 10.1371/journal.pone.0100776.

132. Feagan BG, Choquette D, Ghosh S, Gladman DD, Ho V, **Meibohm B**, Zou G, Xu Z, Shankar G, Sealey DC, Russell AS. The challenge of indication extrapolation for infliximab biosimilars. Biologicals 2014, 42(4), 177-83.

133. **Meibohm B**. Protein engineering for improved pharmacologic characteristics of established monoclonal antibody-based therapeutics. Clinical Pharmacokinetics 2014, 53, 863-4.*

134. Parker RB, Hu ZY, **Meibohm B**, Laizure SC. Effects of Alcohol on Human Carboxylesterase Drug Metabolism. Clinical Pharmacokinetics 2015, 54, 627-38.

135. Chhim RF, Crill CM, Collier HK, Arnold SR, Pourcyrous M, **Meibohm B**, Christensen M. Ethanol Lock Therapy: A Pilot Infusion Study in Infants. Annals of Pharmacotherapy 2015, 49, 431-6.

136. Diao, L, **Meibohm, B**. Tools for Predicting the PK/PD of Therapeutic Proteins. Expert Opinion On Drug Metabolism and Toxicology 2015, 11, 1115-25.*

137. Rathi, C, **Meibohm, B**. Clinical Pharmacology of Bispecific Antibody Constructs. Journal of Clinical Pharmacology 2015, 55 Suppl 3, S21-8.*

138. Zhang Y, Wei X, Bajaj G, Barrett J, **Meibohm B**, Joshi A, Gupta M. Challenges and Considerations for Development of Therapeutic Proteins in Pediatric Patients. Journal of Clinical Pharmacology 2015, 55 Suppl 3, S103-15.

139. Presley C, Abidi A, Suryanwanshi S, Mustafa S, **Meibohm B**, Moore BM. Pre-clinical evaluation of SMM-189, a cannabinoid receptor 2 specific inverse agonist. Pharmacology Research & Perspectives 2015, 3(4), e00159. doi: 10.1002/prp2.159.

140. Bruhn DF, Waidyarachchi SL, Madhura DB, Shcherbakov D, Zheng Z, Liu J, Abdelrahmand YM, Singh AP, Duscha S, Rathi C, Lee RB, Belland RJ, **Meibohm B**, Rosch JW, Böttger EC, Lee RE. Design, Synthesis and Antimicrobial Evaluation of N-Benzyl Aminomethyl Spectinomycins as Therapeutics for Drug-Resistant Respiratory Tract and Sexually Transmitted Bacterial Infections. Science Translational Medicine 2015, 7, 288ra75.

141. Brouwer KL, Aleksunes LM, Brandys B, Giacoia GP, Knipp G, Lukacova V, **Meibohm B**, Nigam SK, Rieder M, de Wildt SN, for the Pediatric Transporter Working Group. Human ontogeny of drug transporters: Review and recommendations of the pediatric transporter working group. Clinical Pharmacology and Therapeutics 2015, 98(3), 266-87.

142. Bruhn DF, Scherman MS, Liu J, Scherbakov D, **Meibohm B**, Böttger EC, Lenaerts AJ, Lee RE. In vitro and in vivo Evaluation of Synergism between Anti-Tubercular Spectinamides and Non-Classical Tuberculosis Antibiotics. Scientific Reports 2015, 5, 13985. doi: 10.1038/srep13985.

143. Sharma A, Weber, B, Wein, M, Hallman, C, **Meibohm, B**. Essential Criteria for Pharmacokinetic Studies Supporting Bioequivalence of Inhaled Tiotropium Bromide Products. Clinical Pharmacology in Drug Development 2016, 5(1), 52-6. doi: 10.1002/cpdd.187.*

144. Gabrielsson J, Weiner D, **Meibohm B**. Pattern recognition in pharmacokinetic data analysis. AAPS Journal 2016, 18(1), 47-63. doi: 10.1208/s12248-015-9817-6.*

145. Gunn GR 3rd, Sealey DC, Jamali F, **Meibohm B**, Gosh S, Shankar G. From the Bench to Clinical Practice: Understanding the Challenges and Uncertainties in Immunogenicity Testing for Biopharmaceuticals. Clinical and Experimental Immunology 2016, 184(2), 137-46. doi: 10.1111/cei.12742.

146. Madhura DB, Liu J, **Meibohm** B, Lee RE. Phase II Metabolic Pathways of Spectinamide Antitubercular Agents: A Comparative Study of the Reactivity of 4-Substituted Pyridines to Glutathione Conjugation. Medicinal Chemical Communications 2016, 7(1), 114-7. doi: 10.1039/C5MD00349K.*

147. Barnes RC, Krenek KA, **Meibohm B**, Mertens-Talcott SU, Talcott ST. Urinary Metabolites from Mango (Mangifera indica L. cv. Keitt) Galloyl Derivatives and In Vitro Hydrolysis of Gallotannins in Physiological Conditions. Molecular Nutrition & Food Research 2016, 60(3), 542-50. doi: 10.1002/mnfr.201500706.

148. Midde NM, Rahman MA, Rathi C, Li J, **Meibohm B**, Li W, Kumar, S. Effect of ethanol on the metabolic characteristics of HIV-1 integrase inhibitor Elvitegravir and Elvitegravir/Cobicistat with CYP3A: An analysis using a newly developed LC-MS/MS method. PLoS ONE 2016; 11(2): e0149225. doi: 10.1371/journal.pone.0149225.

149. Madhura DB, Trivedi A, Liu J, Boyd VA, Jeffries C, Loveless V, Lee RE, **Meibohm B**. Tissue Penetration of a Novel Spectinamide Antibiotic for the Treatment of Tuberculosis. AAPS Journal 2016, 18(3), 788-91. doi: 10.1208/s12248-016-9900-7.*

150. Thomson MM, Hines RN, Schuetz EG, **Meibohm B**. Expression Patterns of OATP 1B1 and OATP 1B3 Protein in Human Pediatric Liver. Drug Metabolism and Disposition 2016, 44(7), 999-1004. doi: 10.1124/dmd.115.069252pii.*

151. Leeder JS, **Meibohm B**. Challenges and Opportunities for Increasing the Knowledgebase Related to Biotransformation and Pharmacokinetic during Growth and Development. Drug Metabolism and Disposition 2016, 44(7), 916-23. doi: 10.1124/dmd.116.071159.*

152. Mould DR, **Meibohm B**. Drug Development of Therapeutic Monoclonal Antibodies. Biodrugs 2016, 30(4):275-93. doi: 10.1007/s40259-016-0181-6.*

153. Liu J, Bruhn DF, Lee REB, Zheng Z, Janusic T, Scherbakov D, Scherman MS, Boshoff HIM, Das S, Raskesh, Waidyarachchi SL, Brewer TA, Gracia B, Yang L, Bollinger JC, Robertson GT, **Meibohm B**, Lenaerts AJ, Ainsa J, Böttger EC, Lee RE. The Structure-Activity Relationships of Spectinamide Antituberculosis agents; a Dissection of Ribosomal Inhibition and Native Efflux Avoidance Contributions. ACS Infectious Diseases 2017, 3(1), 72-88. doi: 10.1021/acsinfecdis.6b00158.

154. Rathi C, Lee RE, **Meibohm B**. Translational PK/PD of Anti-Infective Therapeutics. Drug Discovery Today: Technologies 2016, 21-22:41-49. doi: 10.1016/j.ddtec.2016.08.004.*

155. Herskovitz J, Ryman J, Thway T, Lee S, Zhou L, Chirmule N, **Meibohm B**, Jawa V. Immune Suppression During Preclinical Drug Development Mitigates Immunogenicity Mediated Impact on Therapeutic Exposure. AAPS Journal 2017, 19(2), 447-455. doi: 10.1208/s12248-016-0026-8.

156. Midde NM, Sinha N, Lukka PB, **Meibohm B**, Kumar S. Alterations in cellular pharmacokinetics and pharmacodynamics of elvitegravir in response to alcohol exposure in HIV-1 infected monocytic (U1) cells. PLoS ONE 2017, 12(2):e0172628. doi: 10.1371/journal.pone.0172628.

157. Siricilla S, Mitachi K, Yang J, Eslamimehr S, Lemieux MR, **Meibohm B**, Ji Y, Kurosu MA. New Combination of a Pleuromutilin Derivative and Doxycycline for Treatment of Multidrug-Resistant Acinetobacter baumannii. Journal of Medicinal Chemistry 2017, 60(7):2869-2878. doi: 10.1021/acs.jmedchem.6b01805.

158. Kshirsagar N, Swaminathan S, Jog P, Dalwai S, Mathur R, Shekhar C, **Meibohm B**, Gupta YK, Shafiq N, Sunkara G, Somani VG, Kulkarni P, Tseng B, Mehta D. Regulatory and Ethical Issues in Pediatric Clinical Research: Recommendations From a Panel Discussion. Journal of Clinical Pharmacology 2017, 57(8), 943-946. doi: 10.1002/jcph.916.

159. Sharma A, Weber B, **Meibohm B**. Long pulmonary residence time and plasma half-life of tiotropium: implications for pharmacokinetic bioequivalence studies. Clinical Drug Investigation 2017, 37(7), 705-707. doi: 10.1007/s40261-017-0534-z.*

160. Donnenberg VS, Mandic M, Rhee JC, Burns TF, **Meibohm B**, Korth-Bradley JM. Core Entrustable Professional Activities in Clinical Pharmacology for Entering Residency: Biologics. Journal of Clinical Pharmacology 2017, 57(8), 947-955. doi: 10.1002/jcph.938.

161. He H, Ma D, Crone LB, Butawan M, **Meibohm B**, Bloomer RJ, Yates CR. Assessment of the drug-drug interaction potential between theacrine and caffeine in humans. Journal of Caffeine Research 2017, 7(3), 95-102. doi: 10.1089/jcr.2017.0006.

162. Midde NM, Gong Y, Cory TJ, Li J, **Meibohm B**, Li W, Kumar S. Influence of Ethanol on Darunavir Hepatic Clearance and Intracellular PK/PD in HIV-Infected Monocytes, and CYP3A4-Darunavir Interactions Using Inhibition and in Silico Binding Studies. Pharmaceutical Research 2017, 34(9), 1925-1933. doi: 10.1007/s11095-017-2203-6.

163. Ryman JT, **Meibohm B**. The Pharmacokinetics of Monoclonal Antibodies. CPT Pharmacometrics and Systems Pharmacology 2017, 6(9), 576-588. doi: 10.1002/psp4.12224.*

164. Laizure SC, **Meibohm B**, Nelson K, Chen F, Hu ZY, Parker RB. Comparison of caffeine disposition following administration by oral solution (energy drink) and inspired powder (AeroShot) in human subjects. British Journal of Clinical Pharmacology 2017, 83(12), 2687-2694. doi: 10.1111/bcp.13389.

165. Hohlbaum AM, Gille H, Trentmann S, Kolodziejczyk M, Rattenstetter B, Laarakkers CM, Katzmann G, Christian HJ, Andersen N, Allersdorfer A, Olwill S, **Meibohm B**, Audoly LP, Swinkels DW, van Swelm RPL. Sustained plasma hepcidin suppression and iron

elevation by Anticalin-derived hepcidin antagonist in cynomolgus monkey. British Journal of Pharmacology 2018, 175(7), 1054-1065. doi: 10.1111/bph.14143.

166. Greenblatt DJ, Mager DE, **Meibohm B**, Burckart GJ. In Memoriam: Darrell R. Abernethy 1949-2017. Clinical Pharmacology in Drug Development 2018, 7(2):108-109. doi: 10.1002/cpdd.440.

167. Greenblatt DJ, Mager DE, **Meibohm B**, Burckart GJ. In Memoriam: Darrell R. Abernethy 1949-2017. Journal of Clinical Pharmacology 2018, 58(2):129-30. doi: 10.1002/cph.1078.

168. Diao L, **Meibohm B**. Pharmacometric Applications and Challenges in the Development of Therapeutic Antibodies in Immuno-Oncology. Current Pharmacology Reports 2018, 4(4): 285-291.*

169. Santos K, Lukka PB, Grzegorzewicz A, Jackson M, Trivedi A, Pavan F, Chorilli M, Braunstein M, Hickey A, **Meibohm B**, Gonzalez-Juarrero M. Primary Lung Dendritic Cell Cultures to Assess Efficacy of Spectinamide-1599 Against Intracellular Mycobacterium tuberculosis. Frontiers in Microbiology 2018, 9:1895. doi: 10.3389/fmicb.2018.01895.

170. Chowdhury P, Nagesh PKB, Hatami E, Wagh S, Dan N, Tripathi MK, Khan S, Hafeez BB, **Meibohm B**, Chauhan SC, Jaggi M, Yallapu MM. Tannic acid-inspired paclitaxel nanoparticles for enhanced anticancer effects in breast cancer cells. Journal of Colloid Interface Science 2018, 535:133-148. doi: 10.1016/j.jcis.2018.09.072.

171. Polli JW, McCurdy CR, Wurster DE, DeSilva BS, Bak A, Bendayan R, **Meibohm B**, Templeton AC, Weiser W; AAPS Leadership. The Journey to AAPS 2020: a Reflection from Strategic Planning to PharmSci 360. AAPS Journal 2018 Nov 3;21(1):2. doi: 10.1208/s12248-018-0273-y.

172. Polli JW, McCurdy CR, Wurster DE, DeSilva BS, Bak A, Bendayan R, **Meibohm B**, Templeton AC, Weiser W; AAPS Leadership. The Journey to AAPS 2020: a Reflection from Strategic Planning to PharmSci 360. AAPS PharmSciTech 2018, 19(8), 3325-7. doi: 10.1208/s12249-018-1200-3.

173. Polli JW, McCurdy CR, Wurster DE, DeSilva BS, Bak A, Bendayan R, **Meibohm B**, Templeton AC, Weiser W; AAPS Leadership. The Journey to AAPS 2020: a Reflection from Strategic Planning to PharmSci 360. AAPS Open 2018, 4:8. doi: 10.1186/s41120-018-0028-y.

174. Vaddady PK, Trivedi A, Rathi C, Madhura DB, Liu J, Lee RE, **Meibohm B**. Dynamic time-kill curve characterization of spectinamide antibiotics 1445 and 1599 for the treatment of tuberculosis. European Journal of Pharmaceutical Sciences 2019, 127, 233-9. doi: 10.1016/j.ejps.2018.11.006.

175. Rathi C, Lukka PB, Wagh S, Lee RE, Lenaerts AJ, Braunstein M, Hickey A, Gonzalez-Juarrero M, **Meibohm B**. Comparative pharmacokinetics of spectinamide 1599 after subcutaneous and intrapulmonary aerosol administration in mice. Tuberculosis 2019, 114, 119-122. doi: 10.1016/j.tube.2018.12.006.*

176. Donnenberg VS, Chaikin P, Mandic M, **Meibohm B**, van den Anker J, Rhinehart E, Nafziger AN, Burris JF. Core Entrustable Professional Activities in Clinical Pharmacology

for Entering Residency: Common Problem Drugs and How to Prescribe Them. Journal of Clinical Pharmacology 2019, 59, 915-22. doi: 10.1002/jcph.1389.

177. Zhao W, Leroux S, Allegaert K, Capparelli EV, Biran V, Thomson A, Simon N, **Meibohm B**, Lo YL, Marqués R, Peris JE, Lutsar I, Saito J, Nakamura H, van den Anker JN, Sharland M, Jacqz-Aigrain, E. Population pharmacokinetic meta-analysis of individual data to design the first randomized efficacy trial of vancomycin in neonates and young Infants. Journal of Antimicrobial Chemotherapy 2019, 74(8), 2128-2138. doi: 10.1093/jac/dkz158.

178. Walz A, Lukka PB, Pearce C, Crissen E, Braunstein M, Hickey A, **Meibohm B**, Gonzalez-Juarrero M. Sterilization of Mycobacterium tuberculosis infected samples using methanol preserves anti-tuberculosis drugs for subsequent pharmacological testing studies. Tuberculosis 2019, 117, 52-55. doi: 10.1016/j.tube.2019.06.002.

179. Stewart IA, Lukka PB, **Meibohm B**, Gonzalez-Juarrero M, Braunstein MS, Lee RE, Hickey AJ. Development and Characterization of a Dry Powder Formulation for Anti-Tuberculosis Drug Spectinamide 1599. Pharmaceutical Research 2019, 36(9):136. doi: 10.1007/s11095-019-2666-8.

180. Nagesh PKB, Chowdhury P, Hatami E, Kumari S, Kashyap VK, Tripathi MK, Wagh S, **Meibohm B**, Chauhan SC, Jaggi M, Yallapu MM. Cross linked polyphenol-based drug nano-self assemblies engineered to blockade prostate cancer senescence. ACS Applied Materials & Interfaces 2019, 11, 38357-38554. doi: 10.1021/acsami.9b14738.

181. Shakhnovich V, **Meibohm B**, Rosenberg A, Kierzek AM, Hasenkamp R, Funk RS, van der Graaf P, Wang YM, Hamuro L. Immunogenicity in Clinical Practice and Drug Development: When is it significant? Clinical and Translational Sciences 2020, 13, 219-223. doi: 10.1111/cts.12717.

182. Fuhr L, Hanke N, **Meibohm B**, Lehr T. Effective removal of dabigatran by idarucizumab or hemodialysis – a physiologically based pharmacokinetic modeling analysis. Clinical Pharmacokinetics 2020, 59, 809-825. doi: 10.1007/s40262-019-00857-y.

183. Temrikar ZH, Suryawanshi S, **Meibohm B**. Pharmacokinetics and Clinical Pharmacology of Monoclonal Antibodies in Pediatric Patients. Pediatric Drugs 2020, 22, 199-216. doi: 10.1007/s40272-020-00382-7.*

184. Kovar L, Weber A, Zemlin M, Koh Y, **Meibohm B**, Selzer D, Lehr, T. Physiologically-Based Pharmacokinetic (PBPK) Modeling Providing Insights into Fentanyl Pharmacokinetics in Adults and Pediatric Patients. Pharmaceutics 2020, 12, 908. doi:10.3390/pharmaceutics12100908.

185. Meduri GU, Annane D, Confalonieri M, Chrousos GP, Rochwerg B, Busby A, Ruaro B, **Meibohm B**. Pharmacological principles guiding prolonged glucocorticoid treatment in ARDS. Intensive Care Medicine 2020, 46, 2284-96. doi: 10.1007/s00134-020-06289-8.*

186. Wu Z, Gu L, Zhang S, Liu T, Lukka, PB, **Meibohm B**, Bollinger JC, Zhou M, Li W. Discovery of N-(3,4-dimethylphenyl)-4-(4-isobutyrylphenyl)-2,3,3a,4,5,9b-hexahydrofuro[3,2-c]quinoline-8-sulfonamide as a potent dual MDM2/XIAP inhibitor. Journal of Medicinal Chemistry 2021, 64, 1930-50. doi: 10.1021/acs.jmedchem.0c00932.

187. Lukka PB, Woods M, Chhim R, Phelps SJ, Wheless JW, **Meibohm B**. Use of Real-World Data and Pharmacometric Modeling in Support of Lacosamide Dosing in Pediatric Patients Under Four Years of Age. Journal of Clinical Pharmacology 2021, 61, 881-8. doi: 10.1002/jcph.1840.*

188. **Meibohm B**, Arya V. In Memoriam: Hartmut Derendorf (1953-2020). Journal of Clinical Pharmacology 2021, 61, 423-5. doi: 10.1002/jcph.1847.*

189. **Meibohm B**, Arya V. In Memoriam: Hartmut Derendorf (1953-2020). Clinical Pharmacology in Drug Development 2021, 10, 331-3. doi: 10.1002/cpdd.947.*

190. Tang BH, Guan Z, Allegaert K, Wu YE, Manolis E, Leroux S, Yao BF, Shi HY, Li X, Huang X, Wang WQ, Shen AD, Wang XL, Wang TY, Kou C, Xu HY, Zhou Y, Zheng Y, Hao GX, Xu BP, Thomson AH, Capparelli EV, Biran V, Simon N, **Meibohm B**, Lo YL, Marques R, Peris JE, Lutsar I, Saito J, Burggraaf J, Jacqz-Aigrain E, van den Anker J, Zhao W. Drug Clearance in Neonates: A Combination of Population Pharmacokinetic Modelling and Machine Learning Approaches to Improve Individual Prediction. Clinical Pharmacokinetics 2021, 60, 1435-48. doi: 10.1007/s40262-021-01033-x.

191. Malik PRV, Temrikar ZH, Chelle P, Edginton AN, **Meibohm B**. Pediatric Dose Selection for Therapeutic Proteins. Journal of Clinical Pharmacology 2021, 61 Suppl 1, S193-S206. doi: 10.1002/jcph.1829.*

192. Jonsson C, Golden J, **Meibohm B**. Time to Mind the Gap in Novel Small Molecule Drug Discovery for Direct-Acting Antivirals for SARS-CoV-2. Current Opinion in Virology 2021, 50, 1-7. doi:10.1016/j.coviro.2021.06.008

193. Banerjee S, Mahmud F, Deng S, Wang Y, Yun MK, Fakayode SO, Arnst K, Yang L, Chen H, Wu Z, Lukka PB, Parmar K, **Meibohm B**, White SW, Li W, Miller DD. X-Ray Crystallography Guided Design, Antitumor Efficacy and QSAR Analysis of Metabolically Stable Cyclopenta-Pyrimidinyl Dihydroquinoxalinone as Potent Tubulin Polymerization Inhibitors. Journal of Medicinal Chemistry 2021, 64, 13072-95. doi:10.1021/acs.jmedchem.1c01202.

194. Wagh S, Rathi C, Lukka PB, Parmar K, Temrikar Z, Liu J, Scherman MS, Lee RE, Robertson GT, Lenaert AJ, **Meibohm B**. Model-Based Exposure-Response Assessment for Spectinamide 1810 in a Mouse Model of Tuberculosis. Antimicrobial Agents and Chemotherapy 2021, 65, e0174420. doi: 10.1128/AAC.01744-20.*

195. Gonzalez-Juarrero M, Lukka PB, Wagh S, Walz A, Arab J, Pearce C, Zohaib A, Ryman JT, Parmar K, Temrikar Z, Munoz-Gutierrez J, Robertson GT, Liu J, Lenaerts AJ, Daley C, Lee RE, Braunstein M, Hickey AJ, **Meibohm B**. Preclinical Evaluation of Inhalational Spectinamide-1599 Therapy against Tuberculosis. ACS Infectious Diseases 2021, 7, 2850-63. doi: 10.1021/acsinfecdis.1c00213.*

196. Banerjee S, Yadav S, Banerjee S, Fakayode SO, Parvathareddy J, Reichard W, Surendranathan S, Mahmud F, Whatcott R, Thammathong J, **Meibohm B**, Miller DD, Jonsson CB, Dubey KD. Drug Repurposing to Identify Nilotinib as Potential SARS-CoV-2 Main Protease Inhibitor: An Insight from Computational and In Vitro Study. Journal of Chemical Information and Modeling 2021, 61, 5469-5483. doi:10.1021/acs.jcim.1c00524.

197. **Meibohm B**. Knowledge Gaps in the Pharmacokinetics of Therapeutic Proteins in Pediatric Patients. Frontiers in Pharmacology 2022, 13, 847021. doi:10.3389/fphar.2022.847021.

198. Deng S, Krutilina RI, Hartman KL, Chen H, Parke DN, Wang R, Mahmud F, Ma D, Lukka PB, **Meibohm B**, Seagroves TN, Miller DD, Li W. Colchicine-binding site agent CH-2-77 as a potent tubulin inhibitor suppressing triple-negative breast cancer. Molecular Cancer Therapeutics 2022, 21, 1103-14. doi: 10.1158/1535-7163.MCT-21-0899.

199. Yang B, Parker RB, **Meibohm B**, Temrikar ZH, Srivastava A, Laizure SC. Alcohol Inhibits the Metabolism of Dimethyl Fumarate to the Active Metabolite Responsible for Decreasing Relapse Frequency in the Treatment of Multiple sclerosis. PLOS ONE 2022. Nov 28;17(11):e0278111. doi: 10.1371/journal.pone.0278111

200. Deng S, Banerjee S, Chen H, Pochampally S, Wang Y, Yun MK, White SW, Parmar K, **Meibohm B**, Hartman KL, Wu Z, Miller DD, Li W. SB226, an inhibitor of tubulin polymerization, inhibits paclitaxel-resistant melanoma growth and spontaneous metastasis. Cancer Letters 2023, 555:216046. doi: 10.1016/j.canlet.2022.216046.

201. Maloney SA, Alshiraihi I, Singh A, Stewart IA, Gonzalez JM, Gonzalez-Juarrero M, **Meibohm B**, Hickey AJ. Spray Dried Tigecycline Dry Powder Aerosols for the Treatment of Nontuberculous Mycobacterial Pulmonary Infections. Tuberculosis 2023, 139:102306. doi: 10.1016/j.tube.2023.102306.

202. Michelet R, Aulin LBS, Borghardt JM, Dalla Costa T, Denti P, Ibarra M, Ma G, **Meibohm B**, Pillai G, Schmidt S, Hennig S, Kloft C. Barriers to global pharmacometrics: educational challenges and opportunities across the globe. CPT Pharmacometrics and Systems Pharmacology 2023, 12, 743-7. doi: 10.1002/psp4.12940.

203. Lassiter G, Otsuka R, Hirose T, Rosales I, Karadagi A, Tomosugi T, Dehnadi A, Lee H, Colvin RB, Baardsnes J, Moraitis A, Smith EE, Ali Z, Berhe P, Mulder A, **Meibohm B**, Daugherty B, Fogarty S, Pierson RN, Lederman S, Kawai T. TNX-1500, a crystallizable fragment-modified anti-CD154 antibody, prolongs nonhuman primate renal allograft survival. American Journal of Transplantation 2023 Apr4:S1600-6135(23)00371-4. doi: 10.1016/j.ajt.2023.03.022.

204. Miura S, Habibabady ZA, Pollok F, Ma M, Rosales IA, Kinoshita K, Pratts S, McGrath G, Chaban R, Fogarty S, **Meibohm B**, Daugherty B, Lederman S, Pierson RN. TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival. American Journal of Transplantation 2023 Apr 6:S1600-6135(23)00396-9. doi: 10.1016/j.ajt.2023.03.025.

205. Cao X, Yang D, Parvathareddy J, Chu YK, Kim EJ, Fitz-Henley JN, Li X, Lukka PB, Parmar KR, Temrikar ZH, Dhole P, Adcock RS, Gabbard J, Bansal S, Lee J, Zalduondo L, Hayes E, Stabenow J, **Meibohm B**, Fitzpatrick EA, Bailey K, Campos RK, Julander JG, Rossi SL, Chung D, Jonsson CB, Golden JE. Efficacy of a brain-penetrant antiviral in lethal Venezuelan and eastern equine encephalitis mouse models. Science Translational Medicine 2023 Apr 12;15(691):eabl9344. doi: 10.1126/scitranslmed.abl9344.

206. Sluter M, Bhuniya R, Yuan X, Ramaraju A, Chen Y, Yu Y, Parmar KR, Temrikar ZH, Srivastava A, **Meibohm B**, Jiang J, Yang CY. Novel, Brain-Permeable, Cross-Species

Benzothiazole Inhibitors of Microsomal Prostaglandin E Synthase-1 (mPGES-1) Dampen Neuroinflammation In Vitro and In Vivo. ACS Pharmacology & Translational Science 2023 Mar 21;6(4):587-599. doi: 10.1021/acsptsci.2c00241.

207. Pochampally S, Hartman KL, Wang R, Wang J, Yun MK, Parmar K, Park H, **Meibohm B**, White SW, Li W, Miller DD. Design, Synthesis, and Biological Evaluation of Pyrimidine Dihydroquinoxalinone Derivatives as Tubulin Colchicine Site-Binding Agents That Displayed Potent Anticancer Activity Both In Vitro and In Vivo. ACS Pharmacology & Translational Science 2023 Mar 22;6(4):526-545. doi: 10.1021/acsptsci.2c0010.

208. Temrikar ZH, Kodidela S, Kumar S, Liu J, Robertson GT, Lee RE, Hickey AJ, Gonzalez-Juarrero M, **Meibohm B**. Characterization of Spectinamide 1599 Efficacy Against Different Mycobacterial Phenotypes. Tuberculosis 2023, 140:102342. doi: 10.1016/j.tube.2023.102342.

209. Tang BH, Zhang JY, Allegaert K, Hao GX, Yao BF, Leroux S, Thomson AH, Yu Z, Gao F, Zheng Y, Zhou Y, Capparelli EV, Biran V, Simon N, **Meibohm B**, Lo YL, Marques R, Peris JE, Lutsar I, Saito J, Jacqz-Aigrain E, van den Anker J, Wu, YE, Zhao W. Use of Machine Learning for Dosage Individualization of Vancomycin in Neonates. Clinical Pharmacokinetics 2023, 62(8):1105-16. doi: 10.1007/s40262-023-01265-z.

210. Temrikar ZH, Golden, JE, Jonsson CB, **Meibohm B**. Clinical and Translational Pharmacology Considerations for Anti-Infectives Approved under the FDA Animal Rule. Clinical Pharmacokinetics 2023, 62(7):943-53. doi: 10.1007/s40262-023-01267-x.

211. Parmar KR, Lukka PB, Wagh S, Temrikar ZH, Liu J, Lee RE, Braunstein M, Hickey AJ, Robertson GT, Gonzalez-Juarrero M, Edginton A, **Meibohm B**. Development of a Minimalistic Physiologically-Based Pharmacokinetic (mPBPK) Model for the Preclinical Development of Spectinamide Antibiotics. Pharmaceutics 2023, 15(6):1759. doi: 10.3390/pharmaceutics1506175.

212. Sluter MN, Li Q, Yasmen N, Chen Y, Li L, Hou R, Yu Y, Yang CY, **Meibohm B**, Jiang J. The Inducible Prostaglandin E Synthase (mPGES-1) in neuroinflammatory disorders. Exp Biol Med 2023. Doi: 10.1177/1535370223117.

213. Maloney SE, Stewart IE, Mecham JB, Gonzalez-Juarrero M, **Meibohm, B**, Hickey AJ. Disposable Dosators Intended for Dry Powder Delivery to Mice. Journal of Visual Experiments 2023 Aug 18;(198). doi: 10.3791/65756.

OTHER PUBLICATIONS

Electronic Media

214. **Meibohm B**: Pharmacokinetic and Pharmacodynamic Modeling of Biologics: Understanding New Complexities'. In: *Biotec 101 On-Demand Online Course*, Lecture 4.3, American Association of Pharmaceutical Scientists 2011.*

215. **Meibohm, B**: The pharmacokinetics of therapeutic proteins (2019, March 31) [Video file]. In: *The Biomedical & Life Sciences Collection, Henry Stewart Talks*. Retrieved April 25, 2019, from https://hstalks.com/bs/3913/.*

Professional Press Articles

216. **Meibohm, B**, Beierle, I: Specialization as Survival Strategy in the Age of Rapid Medical Progress, Onkologische Pharmazie 1999, 1, p. 1-2.*

217. Zhang, W, **Meibohm, B**. Abstract and comments on the publication 'The influence of renal function and maturation on vancomycin elimination in newborns and infants' by Capparelli et al., J. Clin Pharmacol 2001, 41:927-34. In: Journal of Pediatric Pharmacology and Therapeutics 2001, 6, p. 525-31.*

218. Jungmayr P, Muller-Bohn T, Meier K, Hanpft U, Krekel H, Barth J, Eckert-Lill C, Dranitsakis G, **Meibohm B**, Fischer FJ. Oncology Pharmacy: Report of the 9th North German Cytostatics Workshop. Deutsche Apotheker Zeitung 2001, 141, 65-79

219. Lam, MSH, Ignoffo, RJ, **Meibohm, B** (Ed.). A Guideline for Clinically-Relevant Drug Interactions in Oncology. (in German) Institute for Applied Healthcare Sciences IFAHS e.V., Flensburg, Germany, January 2004.*

220. **Meibohm**, **B.** How Important are Sex Differences in Pharmacokinetics? Proceedings from Understanding the Biology of Sex Differences; The Fifth Annual Conference on Sex and Gene Expression, Society for Women's Health, Washington, DC 2004, p. 35-37.*

221. **Meibohm, B.** LC-MS/MS Combined with POPPK: Challenges of Pharmacokinetic Evaluations in Pediatric Populations. G.I.T. Laboratory Journal 05/2006, p. 36-7.*

222. Bass, GE, **Meibohm, B**, Dalton, JT, Sayre, R. Free Energy of Activation for the Comorosan Effect. https://arxiv.org/abs/0706.1504; Cornell University Library, 2007, http://arXiv.org

223. Frey, R, Bell, R, Kloth, D, **Meibohm, B**, Vulto, AG, Kuhl, KC. U.S. Prepares Groundwork For Biosimilar Approvals. Clinical Oncology News 2012, 7(5), www.clinicaloncology.com

Abstracts & Proceedings Published and Presented

1. **Meibohm, B,** Führer, C, Kleine, P: Investigations on the Stereoselective Pharmacokinetics of Mexiletine. European Journal of Pharmaceutical Sciences 2 (1994), p. 114. Presented at 2nd European Congress of Pharmaceutical Sciences, EUFEPS/DPhG, Humboldt-University, Berlin, October 1-3, 1994.

2. **Meibohm, B**, Garms, T, Meier, K, Melzer, S: Pharmacoeconomic Benefit of the Implementation of a Patient Oriented Automated Drug Distribution System in Combination with Intensive Advisory Services. European Journal of Clinical Pharmacology 48 (1995), p. A409.
   Presented at 1st International Conference on New Areas in Pharmaceutical Research, Oporto, Portugal, September 21-23, 1995.
3. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Modulation of Lymphocyte Count in Blood by the Circadian Rhythm of Endogenous Cortisol. Journal of Clinical Pharmacology 36 (1996), p. 853.
   Presented at Annual Meeting, American College of Clinical Pharmacology, Philadelphia, PA, September 26-28, 1996.
4. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Cumulative Cortisol Suppression as a Measure of the Systemic Effect of Inhaled Corticosteroids. Journal of Clinical Pharmacology 36 (1996), p. 854.
   Presented at Annual Meeting, American College of Clinical Pharmacology, Philadelphia, PA, September 26-28, 1996.
5. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Circadian Rhythm of Lymphocytes in Blood and its Interrelationship to Endogenous Cortisol. Pharmaceutical Research 13 (1996), (suppl.), p. 446.
   Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Seattle, WA, October 27-31, 1996.
6. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Quantification of Cortisol Suppression as a Measure for the Cumulative Systemic Effect of Corticosteroids. Pharmaceutical Research 13 (1996), (suppl.), p. 446.
   Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Seattle, WA, October 27-31, 1996.
7. **Meibohm, B**, Hochhaus, G, Derendorf, H: Time Dependency of the Pharmacologic Response to Glucocorticoids. Clinical Pharmacology and Therapeutics 61 (1997), p. 155.
   Presented at 98th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, San Diego, CA, March 5-8, 1997.
8. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: A Pharmacokinetic/Pharmacodynamic Approach for Quantifying the Systemic Activity of Inhaled Corticosteroids. Pharmacotherapy 17 (1997), p.195.
   Presented at Spring Practice and Research Forum, American College of Clinical Pharmacy, Panama City, FL, April 6-9, 1997.
9. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: A PK/PD-Approach to Assess the Systemic Activity of Inhaled Corticosteroids as Cumulative Cortisol Suppression. Pharmazie 52 (1997), p. S28.
   Presented at 1st Drug Optimization via Retrometabolism Conference, Amelia Island, FL, May 6-9, 1997.
10. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: PK/PD-Modeling of the Circadian Rhythm of the Lymphocyte Count in Blood Modulated by Endogenous Cortisol. Pharmazie 52 (1997), p. S28.

Presented at 1st Drug Optimization via Retrometabolism Conference, Amelia Island, FL, May 6-9, 1997.

11. Derendorf, H, Hochhaus, G, **Meibohm, B**, Möllmann, H, Barth, J: Pharmacokinetics and Pharmacodynamics of Soft Corticosteroids for Inhalation. Pharmazie 52 (1997), p. S17. Presented at 1st Drug Optimization via Retrometabolism Conference, Amelia Island, FL, May 6-9, 1997.

12. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling of Inhaled Corticosteroids. Proceedings of the 17th Annual Meeting of the Graduate Research Association of Students in Pharmaceutics, Gainesville, FL, June 6-8, 1997.

13. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Predictive Power of PK/PD-Modeling for Inhaled Corticosteroids. Journal of Clinical Pharmacology 37 (1997), p. 865.
    Presented at 26th Annual Meeting, American College of Clinical Pharmacology, Phoenix, AZ, September 18-20, 1997.

14. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Advanced PK/PD-model for the modulation of Lymphocyte Count by Glucocorticoids and Endogenous Cortisol. Journal of Clinical Pharmacology 37 (1997), p. 865.
    Presented at 26th Annual Meeting, American College of Clinical Pharmacology, Phoenix, AZ, September 18-20, 1997.

15. Möllmann, HW, Wagner, M, Stöckmann, R, Derendorf, H, Hochhaus, G, **Meibohm, B**, Barth, J, Krieg, M: Pharmacokinetic/Pharmacodynamic Evaluation after Single-Dose Fluticasone Propionate. Proceedings of the XVIth International Congress of Allergology & Clinical Immunology, Cancun, Mexico, October 19-24, 1997.

16. Wagner, M, Hochhaus, G, Stöckmann, R, Derendorf, H, Barth, J, **Meibohm, B**, Krieg, M, Möllmann, HW: Pharmacokinetics and Pharmacodynamics after Inhaled Administration of Flunisolide. Proceedings of the XVIth International Congress of Allergology & Clinical Immunology, Cancun, Mexico, October 19-24, 1997.

17. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Chronopharmacology of Cortisol Suppression during Inhaled Corticosteroid Therapy. Pharmaceutical Research 14 (1997), (suppl.), p. 141.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Boston, MA, November 3-6, 1997.

18. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Absorption Profiles of Inhaled Corticosteroids. Pharmaceutical Research 14 (1997), (suppl.), p. 141.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Boston, MA, November 3-6, 1997.

19. Hochhaus, G, **Meibohm, B**, Möllmann, H, Derendorf, H, Barth, J, Wagner, M, Krieg, M, Knoeller, J: Pharmacokinetic/Pharmacodynamic Evaluation of Systemic Effects of Budesonide after Oral Delivery. Pharmaceutical Research 14 (1997), (suppl.), p. 617.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Boston, MA, November 3-6, 1997.

20. Hochhaus, G, Derendorf, H, **Meibohm, B**: Pharmacokinetic/Pharmacodynamic Evaluation of Systemic Effects of Inhaled Corticosteroids. Pharmaceutical Research 14 (1997), (suppl.), p. 140.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Boston, MA, November 3-6, 1997.

21. Möllmann, H, Derendorf, H, Barth, J, **Meibohm, B**, Wagner, M, Krieg, M, Knoeller, J, Barth, J, Möllmann, A, Hochhaus, G: Pharmacokinetic/Pharmacodynamic Evaluation of Systemic Effects of Flunisolide after Inhalation. Pharmaceutical Research 14 (1997), (suppl.), p. 140.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, Boston, MA, November 3-6, 1997.

22. **Meibohm, B**, Derendorf, H, Möllmann, H, Wagner, M, Fröehlich, P, Hochhaus, G: Physiologically Based PK/PD-Model for the Interaction between Endogenous and Exogenous Corticosteroids and Lymphocytes. Clinical Pharmacology and Therapeutics 63 (1998), p. 201.
    Presented at 99th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, New Orleans, LA, March 30 - April 1, 1998.

23. **Meibohm, B**, Derendorf, H, Möllmann, H, Wagner, M, Hochhaus, G: Mechanism Based Pharmacokinetic/Pharmacodynamic Model for the Interaction between Endogenous and Exogenous Corticosteroids and Blood Lymphocytes. In: Danhof, M, Steimer, JL (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 157-158.
    Presented at 3rd International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Noordwijkerhout, The Netherlands, May 27-30, 1998.

24. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Chronopharmacological Aspects in Cortisol Suppression during Inhaled Corticosteroid Therapy. In: Danhof, M, Steimer, JL (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 158-159.
    Presented at 3rd International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Noordwijkerhout, The Netherlands, May 27-30, 1998.

25. Hochhaus, G, Derendorf, H, **Meibohm, B**: Effect of Clearance and Volume of Distribution on Pulmonary Targeting of Inhaled Corticosteroids. In: Danhof, M, Steimer, JL (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 155-156.
    Presented at 3rd International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Noordwijkerhout, The Netherlands, May 27-30, 1998.

26. Hochhaus, G, **Meibohm, B**, Stark, J, Möllmann, H, Derendorf, H, Wagner, M: Interaction between Endogenous and Exogenous Corticosteroids and Blood Lymphocytes: The Buffering Capacity of Cortisol Suppression. In: Danhof, M, Steimer, JL (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 156-157.
    Presented at 3rd International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Noordwijkerhout, The Netherlands, May 27-30, 1998.

27. **Meibohm, B**, Kleine, P, Führer, C: Stereoselective Pharmacokinetic Variability of Mexiletine in Patients during Chronic Oral Therapy. AAPS PharmSci 1 (1998), (1, Supplement), S144.
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, San Francisco, CA, November 15-19, 1998.

28. Behn, F, Läer, S, Scholz, H, Mir, TS, Eiselt, M, Venske, A, Weil, J, **Meibohm, B**: Carvedilol in Children with Congestive Heart Failure - Pharmacokinetic Parameters. Naunyn Schmiedeberg´s Archives of Pharmacology 359 (1999), p. R130.

29. Läer, S, Behn, F, Scholz, H, Mir, TS, Eiselt, M, Venske, A, Weil, J, **Meibohm, B**: Carvedilol in Children with Congestive Heart Failure. European Journal of Clinical Pharmacology 55 (1999), p. A30.

30. **Meibohm, B**, Neugebauer, R, Bühring, KU, Schulte, M, Kovar, A: Pharmacokinetics of EMD 132 338 after Escalating Single Oral Doses of Gantofiban, a New Glycoprotein IIB/IIIA Receptor Antagonist. Journal of Clinical Pharmacology 39 (1999), p. 978.
    Presented at 28th Annual Meeting, American College of Clinical Pharmacology, Rockville, MD, September 15-18, 1999.

31. **Meibohm, B**, Schulte, M, Neugebauer, R, Kovar, A: Pharmacokinetic Modeling of the Orally Available Glycoprotein IIb/IIIa Antagonist Gantofiban in Man. AAPS PharmSci 1 (1999), (4, Supplement).
    Presented at AAPS Annual Meeting and Exhibition, American Association of Pharmaceutical Scientists, New Orleans, LA, November 14-18, 1999.

32. Läer, S, Behn, F, Wauer, I, Hulpke-Wette, M, Mir TS, **Meibohm, B**: Pharmacokinetics of Sotalol in Children with Supraventricular Tachycardia. Clinical Pharmacology and Therapeutics 67 (2000), P-II 63, p. 130.
    Presented at 101st Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Los Angeles, CA, March 14 – 18, 2000.

33. Behn, F, Läer, S, Scholz, H, Mir, TS, Weil, J, **Meibohm, B**: Heart Rate and Mean Arterial Pressure During Carvedilol Therapy in Children of Different Ages. Naunyn Schmiedeberg´s Archives of Pharmacology 361 (2000), p. R123.

34. Wauer, I, Läer, S, Behn, F, Scholz, H, Hulpke-Wette, M, Mir, TS, Weil, J, **Meibohm, B**. Sotalol in Pediatric Patients with Supraventricular Tachycardia: Dosage Regimens based on Body Weight or on Body Surface Area? European Journal of Clinical Pharmacology 56 (2000), P. A18.

35. **Meibohm, B**, Brändle, M., Fluck, M., Kovar, A: Pharmacokinetic/ Pharmacodynamic Modeling of the Novel PDE-5 Inhibitor EMD 221 829 in Dogs. AAPS PharmSci 2 (2000), (4, Supplement) #2675.
    Presented at American Association of Pharmaceutical Scientists, Indianapolis, IN, October 27-November 1, 2000.

36. Zhang, W, de Armendi, AJ, Dabbs, K, Anghelescu, D, **Meibohm, B**: An HPLC Method for the Determination of Propofol in Small Volume Human Blood Samples. AAPS PharmSci 2 (2000), (4, Supplement) #1040.
    Presented at American Association of Pharmaceutical Scientists, Indianapolis, IN, October 27-November 1, 2000.

37. Läer, S, Behn, F, Elshoff, JP, Scholz, H, Wauer, I, Hulpke-Wette, M, **Meibohm, B,** Mir, TS, Weil, J. Drug Response in Pediatric Patients with Heart Disease. Naunyn Schmiedeberg´s Archives of Pharmacology 363 (2001), R117.

38. Läer, S, Behn, F, Scholz, H, Mir, TS, Weil, J, **Meibohm, B**. Carvedilol in Pediatric Congestive Heart Failure: Do Young Children behave like Little Adults? Clinical Pharmacology and Therapeutics 69 (2001), p. 52.
Presented at 102nd Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Lake Buena Vista, FL, March 6 – 10, 2001.
Encore presentation at the 30th Annual Meeting, American College of Clinical Pharmacology, Vienna, VA, September 23 – 25, 2001.

39. Läer, S, Wauer, I, Elshoff, JP, **Meibohm, B**, Scholz, H, Mir, TS, Weil J, Hulpke-Wette, M. Effects of Sotalol in Pediatric Patients: Evidence for Developmental Changes in Sotalol's Proarrhythmic and Antiarrhythmic Action. Z Kardiol 90 (2001), II/55.

40. Zhang, W, de Armendi, AJ, Anghelescu, DL, **Meibohm, B**. An HPLC Assay for the Determination of Propofol in Small Volume Blood Samples in Pediatric Anesthesia. Anesthesiology 95 (2001), A485.
Presented at the Annual Meeting of the American Society of Anesthesiologists, New Orleans, LA, October 15-18, 2001.

41. Gupta, M, Tang, L, Yates, CR, Tolley, EA, Wicks, MN, Freire, AX, **Meibohm, B**. Comparative Gene Expression Profiling of Mediators of Inflammation in COPD versus Asthma Patients: Screening for Potential Pharmacodynamic Response Markers. AAPS PharmSci 3 (2001), (4, Supplement) #T3727.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Denver, CO, October 21-25, 2001.

42. Zhang, W, Elshoff, JP, Läer, S, Mir, TS, Hulpke-Wette, M, **Meibohm B**. Population Pharmacokinetics of Sotalol in Pediatric Patients with Tachycardia. AAPS PharmSci 3 (2001), (4, Supplement) #M2311.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Denver, CO, October 21-25, 2001.

43. Larkin, AG, **Meibohm, B**. Comparability of Parameter Estimates Obtained from Different PK/PD Modeling Software. AAPS PharmSci 3 (2001), (4, Supplement) #M2358.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Denver, CO, October 21-25, 2001.

44. Läer, S, Elshoff, JP, Scholz, H, Wauer, I, **Meibohm, B**, Mir, TS, Weil J, Hulpke-Wette, M. Developmental Changes in Proarrhythmic and Antiarrhythmic action of Sotalol in Children with Tachycardia. Circulation 104 (2001), (17 Suppl II), II-488/489.
Presented at the Scientific Sessions, American Heart Association, Anaheim, CA, November 11-14, 2001.

45. Läer, S, Behn, F, Scholz, H, Eiselt, M, Mir, TS, Weil J, **Meibohm, B**. Successful Therapy with Carvedilol in Pediatric Patients with Myocardial Failure. Circulation 104 (2001), (17 Suppl II), II-679.
Presented at the Scientific Sessions, American Heart Association, Anaheim, CA, November 11-14, 2001.

46. Yates, CR, Zhang, W, Song, P, Gaber, AO, Honaker, M, Kotb, M, Alloway, R, and **Meibohm, B**. Effect of CYP3A5 Genotype on Cyclosporine Disposition: A Pilot Study. Clinical Pharmacology and Therapeutics 71 (2002), P-3.
    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, March 24-27, Atlanta, GA.
47. Song, P, **Meibohm, B**, Gaber, AO, Kotb, M, and Yates, CR. Detection of MDR1 Single Nucleotide Polymorphisms (SNPs) C3435T and G2677A Using Real-time PCR. Clinical Pharmacology and Therapeutics 71 (2002), P-102.
    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Atlanta, GA, March 24-27, 2002.
48. Song, P, Dirks, N, Gaber, AO, Kotb, M, **Meibohm, B**, Stuart, L and Yates, CR. Detection of CYP3A5*3 and *6 Using Real-time PCR. Clinical Pharmacology and Therapeutics 71 (2002), P-102.
    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Atlanta, GA, March 24-27, 2002.
49. Talley, CH, Wicks, MN, Freire, AX, Tolley, EA**, Meibohm, B**, and Martin, JC. Correlated of Burden in Spouse Caregivers of Patients with COPD. (accepted). American Journal of Respiratory and Critical Care Medicine 165 (2002), A832.
    Presented at the 98th International Conference, American Thoracic Society, Atlanta, GA, May 17-22, 2002.
50. Sharma, A, Hamelin, BA, Fluck, M, Pibarot, P, Arsenault, M, Dumesnil, J, Pilote, S, **Meibohm, B**. Mechanism-Based PK/PD-Modeling of the Effect of Metoprolol on Cardiac Index. In: Danhof, M, Karlsson, M, Powell, RJ (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 63-64.
    Presented at 4th International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Amsterdam, The Netherlands, April 24-27, 2002.
51. Läer, S, Behn, F, and **Meibohm, B**. Developmental Pharmacodynamics of Carvedilol in Pediatric Patients with Congestive Heart Failure. In: Danhof, M, Karlsson, M, Powell, RJ (eds.) Measurement and Kinetics of In Vivo Drug Effects, Leiden/Amsterdam Center for Drug Research, The Netherlands 1998, p. 35-37.
    Presented at 4th International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Amsterdam, The Netherlands, April 24-27, 2002.
52. Yates, CR, **Meibohm, B**, Zhang, W, Song, P, Li, S, Gaber, AO, Honaker, MR, Kotb, M and Alloway, RR. The effect of CYP3A5 and MDR1 polymorphic expression on cyclosporine oral disposition. Transplantation 74 (2002), V-2113.
53. Song, P, Shukla, N, Schuetz, EG, Zamber, C, **Meibohm, B**, and Yates, CR. Determination of Hepatic MDR1 Expression in African-Americans and Caucasians Using Real-time PCR. AAPS PharmSci 4 (2002), (4, Supplement) #M1100.
    Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Toronto, Canada, November 10-14, 2002.
54. Gupta, M, Freire, AX, Griffin, JG, Headley, AH, Katancik, JA, Kritchevsky, SB, Tolley, EA, Wicks, MN, Yates, CR, **Meibohm, B**. Development of a Real-Time PCR Genotyping Assay

for β2–Adrenergic Receptor (β2–AR) Polymorphisms. AAPS PharmSci 4 (2002), (4, Supplement) #T2244.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Toronto, Canada, November 10-14, 2002.

55. **Meibohm, B**. Application of PK/PD-Concepts for Efficient Drug Development. Eur J Clin Pharmacol 58 (2002), S102.
Presented at 4th Annual Congress for Clinical Pharmacology, Wiesbaden, Germany, November 7-9, 2002.

56. Läer, S, Elshoff, JP, Zhang, W, **Meibohm, B**. Population Pharmacokinetic Modeling for Sotalol in Pediatric Patients with Tachycardia. Eur J Clin Pharmacol 58 (2002), S76.
Presented at 4th Annual Congress for Clinical Pharmacology, Wiesbaden, Germany, November 7-9, 2002.

57. **Meibohm, B**. Exposure-Response vs. Dose-Response Assessments in Drug Development. AGAH 2003, 2: op013. www.biomedcentral.com/browse/abstracts/AGAH/2.
Presented at the Annual Congress Association for Applied Human Pharmacology, Bonn, Germany, February 23-25, 2003.

58. **Meibohm, B**, Zhang, W, Elshoff, JP, Behn, F, Hulpke-Wette, M, Läer, S. Population Pharmacokinetics and Pharmacodynamics of Sotalol in Infants and Children with Tachycardia. Clin Pharmacol Ther 73 (2003), P71
Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Washington, DC, April 2-5, 2003. Encore Presentation at the Annual Meeting of the American College of Clinical Pharmacology, Tampa, FL, September 23-25, 2003.

59. Läer, S, Elshoff, JP, Mir, TS, Müller-Wolf, C, Weil, J, Hulpke-Wette, M, **Meibohm, B**. Dosing Rationale using Population Pharmacokinetics of Sotalol in Children with Tachycardia. Naunyn Schmiedeberg´s Archives of Pharmacology 367 (2003), Suppl. R114.

60. **Meibohm, B**, Gupta, M, Talley, CH, Freire, AX, Wicks, MN, Tolley, EA, Yates, CR. cDNA Array Analysis Indicates Upregulation of CXCR2 and CXCR5 Expression in COPD. Am J Respir Crit Care Med 167 (2003), A939.
Presented at the 99th International Conference, American Thoracic Society, Seattle WA May 16-21, 2003.

61. Christensen, M, **Meibohm, B**, Capparelli, E, Tamborlane W. Single and Multiple Dose Pharmacokinetics of Pioglitazone in Adolescents with Type 2 Diabetes. J Clin Pharmacol 43 (2003), p. 1038.
Presented at the Annual Meeting of the American College of Clinical Pharmacology, Tampa, FL, September 23-25, 2003.

62. Zhang W, Zamber, C, Song, P, Schuetz, EG, Yates, CR, **Meibohm, B**. Developmental Changes of Hepatic P-gp Expression in Pediatric Patients. AAPS PharmSci 5 (2003), (4, Supplement) #W4375.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 26-30, 2003.

63. Gupta, M, Talley, CH. Freire, AX, Wicks, MN, Tolley, EA, Yates, CR, **Meibohm, B**. cDNA-Array Based Gene Expression Profiling Indicates Upregulation of Chemokine Receptors in COPD. AAPS PharmSci 5 (2003), (4, Supplement) #M1073.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 26-30, 2003.

64. Toler, D, Brower, J, Buhse, L, Sadrieh, N, Machado, S, Straughn, A, Yates, R, **Meibohm, B**. Stability and Palatability Evaluation of Ciprofloxacin Hydrochloride Mixed with Food or Drink. AAPS PharmSci 5 (2003), (4, Supplement) #T2003.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 26-30, 2003.

65. Song, P, Zhang, W, Lo, A, **Meibohm, B**, Yates, CR. MDR1 C3435T: Does It Affect Cyclosporine Pharmacodynamics? AAPS PharmSci 5 (2003), (4, Supplement) #W4393.
Presented at Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 26-30, 2003.

66. **Meibohm, B**. How Important are Sex Differences in Pharmacokinetics?
Proceedings from Understanding the Biology of Sex Differences, The Fifth Annual Conference on Sex & Gene Expression, Society for Women's Health Research, Winston-Salem, NC, March 25-28, 2004, pp. 35-37

67. Tang, L, Zhang, W, Gupta, M, Zamber, C, Schuetz, EG, **Meibohm, B**. Ontogeny of Hepatic MDR1, MRP1, AND MRP2 Expression in Human Pediatric Liver Biopsies. J Clin Pharmacol 44 (2004), P71, p. 1202.
Presented at the 33rd Annual Meeting the American College of Clinical Pharmacology, Phoenix, AZ, October 3-5, 2004.

68. Gupta, M, Zhang, L, Tolley, EA, Li, R, Bauer, D, Ding, J, Harris, TB, Newman, AB, Kritchevsky, SB, **Meibohm B**. Racial Differences in the Association of β_2-AR Polymorphisms with the Prevalence and Severity of COPD. J Clin Pharmacol 44 (2004), P82, p. 1204.
Presented at the 33rd Annual Meeting the American College of Clinical Pharmacology, Phoenix, AZ, October 3-5, 2004.

69. Tang, L, Joseph, K, Phelps, S, **Meibohm, B**. Vancomycin Population Pharmacokinetics in Premature and Term Neonates. AAPS J 6 (2004), (Supplement 1), #W4336.
Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, MD, November 7-11, 2004.

70. Song, P, Zhang, L, **Meibohm, B**, Yates, CR. A Preliminary Classification-SAR Model for Pgp Substrate Prediction. AAPS J 6 (2004), (Supplement 1), #W4119.
Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, MD, November 7-11, 2004.

71. Dirks, N, Li, S, Yates, CR, Hochhaus, G, **Meibohm, B**. Relative Anti-Inflammatory Potency of Corticosteroids Measured by AP-1 Inhibitory Activity. AAPS J 6 (2004), (Supplement 1), #T2055.
Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, MD, November 7-11, 2004.

72. Gupta, M, Zhang, L, Tolley, EA, Li, R, Bauer, D, Ding, J, Harris, TB, Newman, AB, Kritchevsky, SB, **Meibohm B**. Racial Differences in the Association of β_2-AR Polymorphisms with the Frequency and Severity of COPD. AAPS J 6 (2004), (Supplement 1), #W5062
    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, MD, November 7-11, 2004.

73. Straughn, A, Sadrieh, N, Yates, CR, **Meibohm, B**, Chen, M-L, Hussain, A. Effect of Sorbitol on Bioequivalence of Ranitidine Oral Solutions. AAPS J 6 (2004), (Supplement 1), #2300.
    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, MD, November 7-11, 2004.

74. Speicher, BT, Gidner, J, Freedman, R, **Meibohm, B**, Warren, M, Hazelwood, M, Leventer, SM, Keogh, JC, Ye, N, Kucharik, RF, Keim, KL. The Effects of Levotofisopam, a Novel Homophthalazine, in a Phase 1B Study Designed to Demonstrate Early Signal Detection in Treatment of the Symptoms of Menopause. Menopause 11 (2004), p. 644.
    Presented at the 2004 Annual Meeting of the North American Menopause Society, Washington, DC, October 6-9, 2004.

75. Laer, S, Albers, S, Gupta, M, **Meibohm, B**. Population Pharmacokinetics of Carvedilol in Pediatric Patients with Congestive Heart Failure. Clin Pharmacol Ther 77 (2005), P88.
    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Orlando, FL, March 2-6, 2005.

76. Tang, L, Gupta, M, Zamber, C, Schuetz, EG, **Meibohm, B**. Ontogeny of Various Solute Carrier Family (SLC) Transporter Expression in Human Pediatric Liver Biopsies. Clin Pharmacol Ther 77 (2005), P95.
    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Orlando, FL, March 2-6, 2005.

77. Dirks, N, Li, S, Hochhaus, G, Yates, CR, Hochhaus, G, **Meibohm, B**. Glucocorticoid Transrepression and Transactivation Potencies as Measured by Inhibition of AP-1, NF-κB and Activation of GRE. AAPS J 7 (2005), (Supplement 2).
    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, TN, November 6-10, 2005.

78. Tangallapally, RP, Budha, NR, Lee, REB, Lenaerts, AJM, **Meibohm, B**, Lee, RE. Determination of basic bioavailability and other pharmacological properties of substituted benzyl nitrofuranyl amides as novel antituberculosis agents. Abstracts of Papers, 231st ACS National Meeting (2006), MEDI-350.
    Presented at the 231st National Meeting of the American Chemical Society, Atlanta, GA, March 26-30, 2006.

79. Dirks, N, Nolting, A, Kovar, A, **Meibohm, B**. Population Pharmacokinetics of Cetuximab in Patients with Squamous Cell Carcinoma. J Clin Pharmacol 46 (2006), 111, p. 1087.
    Presented at the 35th Annual Meeting the American College of Clinical Pharmacology, Cambridge, MA, September 17-19, 2006.

80. Tang, L, Zhang, W, Schuetz, EG, **Meibohm, B**. Age-Dependent Expression of Orphan Nuclear Receptors in Rat Liver. AAPS J 8 (2006), S2, M1355.

Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, October 29 – November 2, 2006.

81. Budha, NR, Mehrotra, N, Tangallapally, R, Lee, RE, **Meibohm, B**. Preclinical Pharmacokinetics of Lee 562, a Novel Nitrofuranylamide Compound for the Treatment of Tuberculosis. AAPS J 8 (2006), S2, T3326.

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, October 29 – November 2, 2006.

82. Mehrotra, N, Tolley, EA, Bauer, DC, Harris TB, Newman, AB, Kritchevsky, SB, **Meibohm, B**. Predictors of Mortality in Elderly Subjects with Obstructive Airway Disease: The PILE Score. Chest 130 (2006), 85S.

    Presented at Chest 2006 – The Annual Meeting of the American College of Chest Physicians, Salt Lake City, UT, October 21 - 26, 2006.

83. Tang, L, Hines, RN, Schuetz, EG, **Meibohm, B**. Age-Associated Expression of P-Glycoprotein and MRP2 in Human Pediatric Liver. Clin Pharmacol Ther 2007, 81, S101

    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Anaheim, CA, March 21-24, 2007.

84. Albers, S, **Meibohm, B**, Barrett, JS, Mir, TS, Laer, S. Appropriate Dosing Schedules for Paediatric Clinical Studies using In Silico Concepts increase Probability of Successful Drug Treatment.

    Presented at the 42nd Annual Meeting of the Association for European Paediatric Cardiology, Warsaw, Poland, May 16-19, 2007.

85. Albers, S, **Meibohm, B**, Mir, TS, Laer , S. Population Pharmacokinetics and Dose Simulation of Carvedilol in Pediatric Patients with Congestive Heart Failure.

    Presented at PAGE 2007 of Population Approach Group in Europe, København, Denmark, June 13-15, 2007.

86. Wancewicz, EV, Siwkowski, A, **Meibohm, B**, Pearce, M, Matson, J, Chew, NYK, Lillie, CE, Tillman, L, Hung, G, Geary, RS, Bhanot, S, Monia, BP. Short (12-Nucleotide) 2nd Generation Antisense Oligonucleotides Selectively Inhibit SGLT2 mRNA Expression Across Multiple Species and are Bioavailable Following Intrajejunal Administration.

    Presented at the 67th Scientific Sessions of the American Diabetes Association, Chicago, IL, June 22-26, 2007.

87. Mehrotra, N, Tang, L, Phelps, SJ, **Meibohm, B**. Evaluation of Vancomycin Dosing Regimens in Preterm and Term Neonates using Monte-Carlo Simulations. J Clin Pharmacol 2007, 47 , 1206.

    Presented at the 36th Annual Meeting the American College of Clinical Pharmacology, San Francisco, CA, September 9-11, 2007.

88. Thomson, MS, Mehrotra, N, **Meibohm, B**. Are trough concentrations a useful pharmacokinetic metric for genetic association studies? AAPS J 2007, 9(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 11-15, 2007.

89. Zhang, Y, Mehrotra, N, Budha, NR, Christensen, ML, **Meibohm B**. LC/MS/MS Assay for the Simultaneous Determination of Acetaminophen, Caffeine, Phenytoin, Ranitidine, and Theophylline in Small Volume Human Plasma Specimens. AAPS J 2007, 9(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 11-15, 2007.

90. Budha, NR, Mehrotra, N, Tangallapally, R, Daniels, A, Lee, RE, **Meibohm, B**. Pharmacokinetically-Guided Lead Optimization for Nitrofuranylamides against Tuberculosis. AAPS J 2007, 9(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 11-15, 2007.

91. Vaddady, PK, Mehrotra, N, Yates, CR, Moore, BM, **Meibohm, B**. Pharmacokinetics in Hemorrhagic Shock: 9-Tetrahydrocannabinol as an Example for a High Extraction Drug. AAPS J 2007, 9(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 11-15, 2007.

92. Tang, L, **Meibohm, B**. Effects of Multidrug Resistance-Associated Protein 2 (Mrp2)-Deficiency on Ceftriaxone Pharmacokinetics. AAPS J 2007, 9(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 11-15, 2007.

93. Wancewicz, EV, Siwkowski, A, **Meibohm, B**, Yates, CR, Pearce, M, Matson, J, Booten, S, Murray, SF, Hung, G, Geary, RS, Bhanot, S, Monia, BP. Long Term Safety and Efficacy of ISIS 388626, An Optimized SGLT2 Antisense Inhibitor, in Multiple Diabetic and Euglycemic Species.

    Presented at the 68th Scientific Sessions of the American Diabetes Association, San Francisco, CA, June 6-10, 2008.

94. Budha, NR, Lee, REB, Lee, RE, **Meibohm, B**. An In Vitro PK/PD Model For Slow-Growing Microorganisms to Determine Time-Kill Curves for Dosing Regimens of Anti-Mycobacterial Drugs. AAPS J 2008, 10(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Atlanta, GA, November 16-20, 2008.

95. Vaddady, PK, Mehrotra, N, Moore, BM, Yates, CR, **Meibohm, B**. Porcine Pharmacokinetics of a Binary Drug Combination of Delta9-Tetrahydrocannabinol and Celecoxib for the Treatment of Hemorrhagic Shock. AAPS J 2008, 10(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Atlanta, GA, November 16-20, 2008.

96. Suryawanshi, S, Kuebler, P, **Meibohm, B**. Semi-Mechanistic Disease Progression Model for Ranibizumab in Age-related Macular Degeneration. J Clin Pharmacol 2009, 49, 1127.

    Presented at the 38th Annual Meeting the American College of Clinical Pharmacology, San Antonio, TX, September 13-15, 2009.

97. Zhang, Y, Christensen, ML, **Meibohm, B**. Simulation-Based Sample Size Optimization for Population Pharmacokinetic Studies in Premature Neonates. AAPS J 2009, 11(S2).

Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Los Angeles, CA, November 8-12, 2009.

98. Vaddady, PK, Rakesh, Qi, J, Lee, RE, **Meibohm, B**. Pharmacokinetically Guided Lead Optimization of A Novel Series of Aminoglycoside Anti-Tuberculosis Agents. AAPS J 2009, 11(S2).

    Presented at the Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Los Angeles, CA, November 8-12, 2009.

99. Dirks, NL, Gastonguay, MR, Gillespie, WR, Knebel, W, Riggs, MM, Panetta, JC, **Meibohm, B**. Comparative Performance of Bayesian Markov Chain Monte Carlo and Maximum Likelihood Population Estimation Methods when Applied to Nonlinear Pharmacokinetics of Monoclonal Antibodies. Clin Pharmacol Ther 2010, 87, S94.

    Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Atlanta, GA, March 17-20, 2010.

100. Yarger, J, **Meibohm, B**, Gately, S, Weitman, S, Nye, SH. NDC-1308 inhibits growth of lung and pancreatic tumors in-vivo by blocking chromosome replication of cancer cells.

    Presented at AACR 101st Annual Meeting, April 17-21, 2010.

101. Lee, DS, De Rekeneire, N, Jeffery, S, Gill, T, Leo-Summers, L, **Meibohm, B**, Bauer, D, Harris, TB, Hanlon, JT. Medication Complexity in a Population of Community-Living Older Persons: The Health, Aging and Body Composition Study

    Presented at the American Geriatrics Society 2010 Annual Meeting, Orlando, FL, May 12-15.

102. Aldrich MC, Kritchevsky S, **Meibohm B**, Leak T, Harris TB, Kumar R, Ziv E, Burchard EG, for the Health ABC Study. Lower Lung Function For African Americans With High African Genetic Ancestry and Tobacco Smoke Exposure: A Gene-Environment Interaction.

    Presented at the American Thoracic Society International Conference, New Orleans, LA, May 14-19, 2010.

103. Suryawanshi, S, Zhang, Y, Kuebler, P, **Meibohm B**. External Qualification of a Semi-Mechanistic Disease Progression Model for Ranibizumab in Age-Related Macular Degeneration. J Clin Pharmacol 2010, 50, 1093.

    Presented at the 39th Annual Meeting the American College of Clinical Pharmacology, Baltimore, MD, September 12-14, 2010.

104. Zhang, Y, Christensen, ML, **Meibohm, B**. Simulation-Based Sample Size Optimization to Support a Population Pharmacokinetic Study Design in Premature Neonates. J Clin Pharmacol 2010, 50, 1091.

    Presented at the 39th Annual Meeting the American College of Clinical Pharmacology, Baltimore, MD, September 12-14, 2010.

105. Vaddady, PK, Hurdle, JG, Liu, J, Rakesh, Lee, RE, **Meibohm, B**. Pharmacokinetic Evaluation of a Novel Spectinamide Series of Antituberculosis Agents. AAPS J 2010, 12, S2.

    Presented at the Pharmaceutical Sciences World Congress/AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, New Orleans, LA, November 14-18, 2010.

106. van den Borst B, Koster A, Yu H, Gosker H, **Meibohm B**, Bauer D, Kritchevsky S, Liu Y, Newman A, Harris T, Schols A. Striking Similarities In Body Composition And Muscle Strength Between Elderly Persons With Obstructive Lung Disease And Smokers With Normal Lung Function. Am J Respir Crit Care Med 183;2011:A1494

Presented at the 2011 American Thoracic Society (ATS) International Conference in Denver, Colorado, May 15, 2011.

107. van den Borst, B, Gosker, H, Koster, A, Kritchevsky, S, Liu, Y, **Meibohm, B**, Rice, T, Shlipak, M, Harris, T, Schols, A. Obstructive Lung Disease is associated with increased abdominal visceral fat and elevated systemic adipocytokines.

Presented at the European Respiratory Society 2011.

108. Trivedi, A, Vaddady, P, Bhattacharjee, H, Lee, R, **Meibohm, B**. Solubilizing Formulations as an Approach to Increase the Oral Bioavailability of Novel Nitrofuranylamide Drug Candidates for the Treatment of Tuberculosis. AAPS J 2011, 13, S2.

Presented at the 25th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, October 23-27, 2011.

109. Zhang, Y, Christensen, A, Christensen, M, **Meibohm, B**. Population Pharmacokinetics of Caffeine in Premature Infants. AAPS J 2011, 13, S2.

Presented at the 25th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, October 23-27, 2011.

110. Limothai, W, **Meibohm, B**. Effect of Dose on the Apparent Bioavailability of Therapeutic Proteins that Undergo Target-Mediated Drug Disposition. AAPS J 2011, 13, S2.

Presented at the 25th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, October 23-27, 2011.

111. Madhura, D, Trivedi, A, Liu, J, Lee, R, **Meibohm, B**. In Vivo Pharmacokinetics of spectinamides for the Treatment of Tuberculosis. AAPS J 2011, 13, S2.

Presented at the 25th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, October 23-27, 2011.

112. Trivedi, A, Madhura, DB, Liu, J, Kromke, K, Rathi, C, Loveless, V, Lee, RE, **Meibohm, B**. Tissue Distribution and Macrophage Uptake for Novel Spectinamide Drug Candidates Against Tuberculosis.

Presented at 52nd Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September 9-12, 2012.

113. Madhura, DB, Trivedi, A, Rathi, C, Liu, J, Loveless, V, Lee, RE, **Meibohm B**. Biodistribution and Pharmacokinetics of Tritium Labeled-Lee 1329 3HBr, A Novel Spectinamide Antibiotic Against Tuberculosis. AAPS J 2012, 14, S2.

Presented at the 26th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Chicago, IL, October 14-18, 2012.

114. Madhura, DB, Trivedi, A, Rathi, C, Liu, J, Lee, RE, **Meibohm, B**. Pharmacokinetic Evaluation of Novel Spectinamides. AAPS J 2012, 14, S2.

Presented at the 26th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Chicago, IL, October 14-18, 2012.

115. Swaminathan, S, Li, H, Palamoor, M, Madhura, D, Moore, BM, **Meibohm, B**, Jablonski, MM. Assessment of safety, in vitro stability, ocular pharmacokinetics and biodistribution of a novel endogenous glycan for retinal diseases. AAPS J 2012, 14, S2.

Presented at the 26th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Chicago, IL, October 14-18, 2012.

116. Thomson, MMS, Hines, RN, Schuetz, EG, **Meibohm, B**. Age-Associated Expression of OATP1B1 and OATP1B3 in Human Pediatric Liver. AAPS J 2012, 14, S2.

Presented at the 26th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Chicago, IL, October 14-18, 2012.

117. Limothai, W, **Meibohm, B**. Factors Affecting Bioavailability Estimation of Therapeutic Proteins Undergoing Target-Mediated Drug Disposition. AAPS J 2012, 14, S2.

Presented at the 26th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Chicago, IL, October 14-18, 2012.

118. Hohlbaum, AM, Allersdorfer, A, Andersen, N, Christian, J, Gille, H, Huelsmeyer, M, Katzmann, G, Mayr, M, **Meibohm, B**, Trentmann, S, Audoly, LP. PK/PD-Guided Development of a Novel Hepcidin Antagonist for the Treatment of Functional Iron Deficiency in CKD. J Am Soc Nephrol 2012, 23: Supplement FR-PO838

Presented at Kidney Week, San Diego, CA, October 30 – November 4, 2012.

119. **Meibohm, B**, Brockhaus, B, Kovar, A, Zuehlsdorf, M. PK/PD Model-Based Drug Development of EMD 525797, a Novel Anti-av Integrin Monoclonal Antibody. Clinical Pharmacology and Therapeutics 2013, 93, Supp 1, S81

Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Indianapolis, IN, March 5-9, 2013.

120. Gonzalez Juarrero, M, Woolhiser, LK, Hastings, CI, Scherman, MS, Liu, J, Böttger, EC, McNeil, MR, **Meibohm, B**, Lee, RE, Lenaerts, AJ. Enhanced in vivo Efficacy of a Novel Spectinamide Compound by Intrapulmonary Aerosol Delivery Using a Murine Model of TB Infection.

Presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10 – 13, 2013.

121. Madhura, D, Trivedi, A, Rathi, C, North, EJ, Lee, RE, **Meibohm, B**. Pharmacokinetic Evaluation of Adamantyl-Phenyl Ureas, A Novel Series of Anti-Tuberculosis Drug Candidates.

Presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10 – 13, 2013.

122. Rathi, C, Madhuara, D, Trivedi, A, Ryman, Liu, J, Lee, RE, Edginton, AN, **Meibohm, B**. Physiological Model-Based Prediction of the Human Pharmacokinetics of Lee1599, a Novel Anti-tuberculosis Agent.

Presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10 – 13, 2013.

123. Trivedi, A, Rathi, C, Madhura, D, Liu, J, Lee, LE, **Meibohm, B**. An In Vitro PK/PD Model-Based Pharmacodynamic Evaluation of Lee 1599, a Novel Spectinamide Antituberculosis Agent

Presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10 – 13, 2013.

124. Ryman, J, Tang, L, Kasek, S, Schuetz, EG, Hines, RN, **Meibohm, B**. Developmental Pharmacogenomics of Transporters ABCB1 (MDR1) and ABCC2 (MRP2) in Pediatric Liver. Clinical Pharmacology in Drug Development 2013, 2, S1, p. 17.

Presented at the 2013 American College of Clinical Pharmacology Annual Meeting, Bethesda, MD, September 22-24, 2013.

Encore presentation at the 27th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 10-14, 2013.

125. Trivedi, A, Madhura, DB, Rathi, C, Liu, J, Lee, RE, **Meibohm, B**. An In Vitro PK/PD Model-Based Pharmacodynamic Evaluation of Lee 1599, a Novel Spectinamide Antituberculosis Agent.

Presented at the 27th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 10-14, 2013.

126. Ryman, J, Edginton, A, Tang, L, **Meibohm, B**. PBPK Simulation of the Effect of ABCC2 and ABCB1 Ontogeny on Ceftriaxone Pharmacokinetics.

Presented at the 27th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 10-14, 2013.

127. Rathi, C, Madhura, DB, Trivedi, A, Ryman, J, Liu, J, Lee, R, Edginton, A, **Meibohm B**. Physiological Model-Based Prediction of the Human Pharmacokinetics of Lee1599, a Novel Anti-tuberculosis Agent.

Presented at the 27th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 10-14, 2013.

128. Rawal, S, Schuck, V, Shankaran, H, **Meibohm, B**. Semi-Mechanistic PK/PD Modeling to Predict Target Tissue Concentrations of Antibiotics and to Correlate PK/PD Relationships from in vitro Kill Kinetics with Pre-clinical Efficacy.

Presented at the 7th Noordwijkerhout Symposium on Pharmacokinetics, Pharmacodynamics and Systems Pharmacology, Leiden Academic Centre for Drug Research, Leiden University, Amsterdam, The Netherlands, April 23-25, 2014.

129. Ryman J, Herskovitz J, Talbot J, Lee S, Thway T, Chirmule N, **Meibohm, B**, Jawa, V. Impact of Immune Suppression on the Pharmacokinetics of a Fully Human Antibody when Administered to a Preclinical Rodent Model.

Presented at the 2014 AAPS National Biotechnology Conference, San Diego, CA, May 19-21, 2014.

130. Chhim R, Crill C, Collier H, Arnold S, Pourcyrous M, **Meibohm B**, Christensen M. Ethanol Lock Therapy: A Pilot Safety Study in Infants

Presented at the 2014 AACP Annual Meeting, Dallas, TX, July 26-30, 2014.

131. Madhura DB, Rathi C, Trivedi A, Waidyarachchi S, Lee RE, **Meibohm B**. Pharmacokinetic Evaluation of Novel Amino-Spectinomycin Antibiotics. Poster number W5309.

Presented at the 28th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 2-6, 2014.

132. Rathi C, Madhura DB, Trivedi A, Lee RE, Lenaerts A, Gonzalez-Juarrero M, **Meibohm B**. Pharmacokinetics of the Spectinamide Antibiotic Lee1599 after Pulmonary Administration. Poster number: W4251.

Presented at the 28th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 2-6, 2014.

133. Trivedi A, Bruhn D, Rathi C, Madhura DB, Liu J, Lee RE, **Meibohm B**. Quantitative Assessment of the Pharmacodynamic Interaction between the Novel Spectinamide Antituberculosis Agent Lee1599 and Rifampicin Using A 3D-Response Surface Approach. Poster number: W5314.

Presented at the 28th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 2-6, 2014.

134. Midde NM, Rathi C, **Meibohm B**, Kumar S. Effect of alcohol on the metabolism of antiretroviral drugs darunavir, darunavir/ritonavir, and elvitegravir: An analysis using liquid chromatography–tandem mass spectrometry.

Presented at NIAAA NeuroAIDS and alcohol abuse satellite meeting 2015.

135. Ryman JT, **Meibohm B**. Modeling the Impact of Antidrug Antibody Formation on the Pharmacokinetics of a Fully Human Monoclonal Antibody in a Preclinical Rodent Model. Journal of Pharmacokinetics and Pharmacodynamics 2015, 42, S98.

Presented at the 6th American Conference on Pharmacometrics (ACOP), Washington, DC, October 4-7, 2015.

136. Rathi C, Madhura D, Trivedi T, Liu J, Scherman M, Robertson G, Lee RE, Lenaerts AJ, **Meibohm B**. Pharmacokinetic-Pharmacodynamic Analysis of Spectinamide Antibiotic Lee1599 in Mycobacterium tuberculosis Infected Mice. Journal of Pharmacokinetics and Pharmacodynamics 2015, 42, S97.

Presented at the 6th American Conference on Pharmacometrics (ACOP), Washington, DC, October 4-7, 2015.

137. Lenaerts AJ, Robertson GT, Scherman MS, Liu J, **Meibohm B**, Boettger EC, Butler, MM, Bowlin TL, Lee RE. Spectinamides: a new class of semisynthetic protein synthesis inhibitors against tuberculosis that overcome native drug efflux. International Journal of Tuberculosis and Lung Disease 2015, 12: Suppl. 2, S155.

Presented at the 46th Union World Conference on Lung Health, Cape Town, South Africa, December 2-6, 2015.

138. Limothai W, **Meibohm B**. Effect of Developmental Growth and FcRn Expression on the Pharmacokinetics of Monoclonal Antibodies in Mice.

Presented at World Conference on Pharmacometrics, Brisbane, Australia, August 21-24, 2016.

139. Rathi C, Robinson GT, Schermann M, Liu J, Lee RE, Lenaerts AJ, **Meibohm B**. Dose-Exposure Response Analysis of Spectinamide Antibiotic Lee 1810 in Mycobacterium tuberculosis Infected Mice. Poster number: 07T0130

Presented at the 30th AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Denver, CO, November 13-17, 2016.

140. Durham P, Lukka P, Braunstein M, Gonzalez-Juarrero M, **Meibohm B**, Lee R, Hickey A. Preparation and Characterization of a Spectinamide-1599 Dry Powder Aerosol for Tuberculosis Therapy. Poster number M7042.

Presented at the 31st AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, San Diego, CA, November 12-15, 2017.

141. Wagh S, Rathi C, Lukka PB, Parmar K, Temrikar Z, Liu J, Scherman MS, Lee RE, Robertson GT, Lenaerts AJ, **Meibohm B**. PK/PD Modeling of Spectinamide 1599 in Mycobacterium tuberculosis Infected Mice. Poster number W022, Journal of Pharmacokinetics and Pharmacodynamics 2018, 45, Suppl. 1, S99

Presented at the 9th American Conference on Pharmacometrics (ACOP), San Diego, CA, October 7-10, 2018.

142. Lukka PB, Wagh S, Durham PG, Arab J, Ryman J, Lee RE, Braunstein M, Gonzalez-Juarerro M, Hickey AJ, **Meibohm B**. Spectinamide 1599 for Drug-Resistant Tuberculosis can be Effectively Delivered by Intratracheal Dry Powder Aerosol Administration in Mice. M1530-02-009.

Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, November 4-7, 2018.

143. Stewart I, Arab J, Walz A, Gonzalez-Juarrero M, Braunstein M, **Meibohm B**, Hickey AJ. Dry Powder Fomulations of Newly-Developed Anti-Tuberculosis Drug Spectinamide 1599. Poster W1230-09-071.

Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, Washington, DC, November 4-7, 2018.

144. Gonzalez-Juarrero M, Lukka P, Wagh S, Arab J, Walz A, Braunstein M, Hickey A, **Meibohm B**. Aerosol spectinamide-1599 therapy against tuberculosis. PS01-407-25. International Journal of Tuberculosis and Lung Disease 2018, 22(11), S153. .

Presented at the 49th Union World Conference on Lung Health, The Hague, Netherlands, October 24-27, 2018.

145. Sullivan G, Kiu R, **Meibohm B**, Lederman, S. Steady-State Pharmacokinetic Properties of a SublingualFormulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL): Comparison to Simulations of Oral Immediate Release Cbp

Presented at the Annual Meeting of the American Society of Clinical Psychopharmacology, Scottsdale, AZ, May 28-31, 2019

146. Lukka PB; Woods M, Chhim R, Phelps SJ, Wheless JW, **Meibohm B**. Pediatric Exposure of Lacosamide Adjunctive Anti-Epileptic Therapy. Clinical Pharmacology in Drug Development 2018, 8(S1), 36

Presented at 2019 Annual Meeting of the American College of Clinical Pharmacology, Chicago, IL, September 8-11, 2019.

147. Parmar, KR, Lukka PB, Wagh S, Temrikar ZH, Lee RE, Braunstein, M, Hickey AJ, Gonzalez-Juarrero M, **Meibohm B**. Prediction of Pulmonary Pharmacokinetics of Spectinamide 1599 in Humans based on Rodent Pharmacokinetic Data using a Permeability-Limited Lung Physiologically Based Pharmacokinetic Model. Poster W0930-13-86.

    Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 3-6, 2019.

148. Temrikar ZH, Wagh S, Lukka PB, Parmar, KR, Lee RE, **Meibohm B**. Establishment of a Hollow Fiber Infection Model for Preclinical PK/PD Evaluation of Novel Spectinamide Antituberculosis Agents. Poster T1530-13-86.

    Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, San Antonio, TX, November 3-6, 2019.

149. Gupta P, Srivastava A, Ryman J, Swanson M, Jawa V, **Meibohm B**. Effect of Immunosuppressive Drugs on Systemic Exposure of a Human Monoclonal Antibody in Rats.

    Presented at the 2022 AAPS National Biotechnology Conference, Anaheim, CA, May 9-12, 2022.

150. Gupta P, Srivastava A, Ryman J, Swanson M, Jawa V, Meibohm B. Short-Term Administration with Immunosuppressants Suppresses Preclinical Immunogenicity Against a Human Monoclonal Antibody in Rats.

    Presented at the 2022 AAPS National Biotechnology Conference, Anaheim, CA, May 9-12, 2022.

151. Maloney SE, Alshiraihi I, Gonzalez JM, **Meibohm B**, Gonzalez-Juarrero M, Hickey AJ. Treatment of Non-Tuberculous Mycobacterial Infections via Spray Dried Tigecycline Dry Powder Aerosols.

    Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, Boston, MA, October 16-19, 2022.

152. Srivastava A, Walz A, Maloney S, Stewart I, Hickey AJ, Braunstein M, Lee RE, Gonzalez-Juarrero M, **Meibohm B**. Spectinamide 1599 exposure in Lung, ELF and Plasma after Passive Inhalation in Mice. Poster T1430-02-08

    Presented at the AAPS PharmSci360 Meeting and Exposition, American Association of Pharmaceutical Scientists, Boston, MA, October 16-19, 2022.

153. Jonsson CB, Kong D, Golden JE, **Meibohm B**, Chung DH, Julander JG. Prophylactic and therapeutic efficacy of a novel brain-penetrant antiviral in lethal mouse models of Venezuelan and eastern equine encephalitis.

    Presented at the International Society for Antiviral Research, Lyon, France, March 13-17, 2023.

154. Gupta P, Gadkari S, Kozhich A, Ryman J, Jawa V, **Meibohm B**. Short-term Tacrolimus/Sirolimus Combination Therapy Induces Long-term Immune Tolerance to a Human Monoclonal Antibody in Rats.

    Presented at the 2023 AAPS National Biotechnology Conference, Philadelphia, PA, April 23-26, 2023.

Abstracts Presented But Not Published in Print

155. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Absorption Characteristics of Corticosteroids after Inhaled Application from Pressurized Metered Dose Inhalers. 5th Annual Joint University of South Carolina / Medical University of South Carolina Pharmaceutical Sciences Symposium, Columbia, SC, April 3, 1998.

156. **Meibohm, B**, Derendorf, H, Möllmann, H, Wagner, M, Fröehlich, P, Hochhaus, G: Corticosteroid Induced Lymphocytopenia as an Example for Mechanism-Based, Physiological PK/PD-Modeling. 5th Annual Joint University of South Carolina / Medical University of South Carolina Pharmaceutical Sciences Symposium, Columbia, SC, April 3, 1998.

157. **Meibohm, B**, Hochhaus, G, Möllmann, H, Barth, J, Derendorf, H: Chronopharmacologic Aspects in the Benefit-To-Risk Ratio of Inhaled Corticosteroid Therapy. 5th Annual Joint University of South Carolina / Medical University of South Carolina Pharmaceutical Sciences Symposium, Columbia, SC, April 3, 1998.

158. Meier, K, Melzer, S, Garms, T, Wölm, S, Blake, K, **Meibohm,** B. Economic and Quality Benefit of a Patient-Oriented Automated Drug Distribution System Combined with Intensive Advisory Service. 6th congress of the European Association of Hospital Pharmacists, Amsterdam, The Netherlands, March 21-23, 2001.

159. Zhang, W, de Armendi, AJ, Dabbs, K, Anghelescu, D**, Meibohm, B**: An HPLC Assay for the Determination of Propofol in Small Volume Blood Samples in Pediatric Anesthesia. St. Jude Children's Research Hospital Faculty/Postdoctoral Poster Session, November 15, 2001.

160. Gupta, M, Yates, CR, **Meibohm, B**. Development of a Real-Time PCR Genotyping Assay for β2-Adrenergic Receptor (β2-AR) Polymorphisms. Presented at the AAPS Southern Regional Discussion Group Annual Meeting, Little Rock, AR, May 29-30, 2003.

161. Zhang W, Zamber, C, Song, P, Schuetz, EG, Yates, CR, **Meibohm, B**. Developmental Changes of Hepatic P-gp Expression in Pediatric Patients. Presented at the AAPS Southern Regional Discussion Group Annual Meeting, Little Rock, AR, May 29-30, 2003.

162. Gupta, M, Zhang, L, Tolley, EA, Li, R, Bauer, D, Ding, J, Harris, TB, Newman, AB, Kritchevsky, SB, **Meibohm B**. Racial Differences in the Association of β_2-AR Polymorphisms with the Frequency and Severity of COPD. Presented at PharmForum 2004, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 17-18, 2004.

163. Tang, L, Joseph, K, Phelps, S, **Meibohm, B**. Vancomycin Population Pharmacokinetics in Premature and Term Neonates.
Presented at PharmForum 2004, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 17-18, 2004.

164. **Meibohm, B**. Clinical Pharmacology and Pharmacy of Oligonucleotide Drug Candidates. Proceedings of the 1st PharmSciFair, Pharmaceutical Sciences Fair & Expedition, Nice, France, June 12-17, 2005.

165. Budha, NR, Mehrotra, N, Tangallapally, R, Lee, R, **Meibohm, B**. Preclinical Pharmacokinetics of Lee 562, a Novel Nitrofuranylamide Compound for the Treatment of Tuberculosis.
Presented at South East Regional Interdisciplinary Symposium (SERIS) – University of Florida, Gainesville, FL, May 19-21, 2006.

166. Mehrotra, N, Tolley, EA, Kritchvsky, SB, **Meibohm, B**. A Simple SAS Macro to Generate P- and T-Bootstrap Confidence Intervals for Hazard Ratios: Application to Cox Proportional Hazard Modeling.
Presented at PharmForum 2007, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 30-31, 2007.

167. Vaddady, PK, Mehrotra, N, Yates, CR, Moore, BM, **Meibohm, B**. Pharmacokinetics in Hemorrhagic Shock: Detal-9-Tetrahydrocannabinol as an Example for a High Extraction Drug.
Presented at PharmForum 2007, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 30-31, 2007.

168. Albers, S, **Meibohm, B**, Barrett, JS, Mir, TS, Laer, S. Population Pharmacokinetics and Dose Simulation of Carvedilol in Pediatric Patients with Congestive Heart Failure.
Presented at 2007 Population Approach Group in Europe meeting, Copenhagen, Denmark, June 13-15, 2007

169. Thomson, MMS, Mehrotra, N, **Meibohm, B**. An Evaluation of the Use of Trough Levels in Trials of Cyclosporine and Tacrolimus Using Clinical Trial Simulation.
Presented at PharmForum 2008, the AAPS Southern Regional Discussion Group Annual Meeting, Little Rock, AR, May 18-20, 2008.

170. Budha, NR, Lee, REB, Lee, RE, **Meibohm, B**. An In Vitro Model for Slow-Growing Microrganisms to Determine Time-Kill Curves for Dosing Regimens of Antimycobacterial Drugs.
Presented at PharmForum 2008, the AAPS Southern Regional Discussion Group Annual Meeting, Little Rock, AR, May 18-20, 2008.

171. Vaddady, PK, Mehrotra, N, Yates, CR, Moore, BM, **Meibohm, B**. Porcine Pharmacokinetics of a Binary Drug Combination of Δ9-Tetrahydrocannabinol and Celecoxib for the Treatment of Hemorrhagic Shock.
Presented at PharmForum 2008, the AAPS Southern Regional Discussion Group Annual Meeting, Little Rock, AR, May 18-20, 2008.

172. Yarger, J, Wood, G, Bhattacharjee, H, **Meibohm, B**, Hershberger, P. Estradiol analogs possessing novel activities for killing cancers.
Presented at Gordon Research Conference, Hormone Action in Development & Cancer, Holderness, NH, July 26-31, 2009.

173. Aldrich, MC, Kritchevsky, S, **Meibohm, B**, Leak, T, Harris, T, Kumar, R, Ziv, E, Burchard, EG for the Health ABC Study. African ancestry-tobacco interaction accelerates lung function decline among African Americans.
Presented at the 59th Annual Meeting of The American Society of Human Genetics, Honolulu, HI, October 22, 2009.

174. Kelmer, G, Bell, GC, Martin-Jimenez, T, Saxton, AM, Catasus, C, Elliot, SB, **Meibohm, B.** Regional Limb Perfusion Using Proximal Veins.
Presented at the 2009 American College of Veterinary Surgeon Veterinary Symposium, Washington, DC, October 6-7, 2009.

175. Suryawanshi, S, Mehrotra, N, Kuebler, P, **Meibohm, B**. Empirical Disease Progression Model for Ranibizumab in Age Related Macular Degeneration.
Presented at the American Conference on Pharmacometrics (ACoP), Mashantucket, CT, October 4-7, 2009.

176. Liu, J, Rakesh, Hurdle, JG, Vaddady, PK, Qi, J, Sun, D, Hevener, KE, **Meibohm, B**, Lenaerts, AE, Lee, RE. Discovery of Spectinamides as Novel Anti-Tubercular Agents.
Presented at Gordon Research Conference on New Antibacterial Drug Discovery & Development, March 14-19, 2010, Galveston, TX.

177. Dirks, NL, Gastonguay, MR, Gillespie, WR, Knebel, W, Riggs, MM, Panetta, JC, **Meibohm, B**. Comparative Performance of Bayesian Markov Chain Monte Carlo and Maximum Likelihood Population Estimation Methods when Applied to Nonlinear Pharmacokinetics of Monoclonal Antibodies.
Presented at 6th International Symposium on Measurement and Kinetics of In Vivo Drug Effects, Leiden, The Netherlands, April 21-24, 2010.

178. Vaddady, PK, Hurdle, J, Liu, J, Rakesh, Lee, RE, **Meibohm, B**. Novel screening approach for evaluating PK/PD properties of a spectinamide series of antituberculosis agents.
Presented at PharmForum 2010, the AAPS Southern Regional Discussion Group Annual Meeting, Oxford, MS, May 23-25, 2010.

179. Kelmer, G, Bell, GC, Martin-Jimenez, T, Saxton, AM, Catasus, C, Elliot, SB, **Meibohm, B.** Regional Limb Perfusion Using Proximal Veins.
Presented at the 5th International Conference on Antimicrobial Agents in Veterinary Medicine, Tel Aviv, Israel, May 11-15, 2010.

180. Rakesh, Hurdle, JG, **Meibohm, B**, Vaddady, P, Budha, N, Woolhiser, L, Lenaerts, A, Lee RE. Development of nitroaromatic antimicrobial agents to treat tuberculosis.
Presented at 10th Winter Conference on Medicinal & Bioorganic Chemistry, Steamboat Springs, CO, January 23, 2011.

181. Madhura, DB, Trivedi, A, Liu, J, Lee, RE, **Meibohm, B**. *In-vivo* pharmacokinetics of spectinamides for the treatment of tuberculosis.
Presented at PharmForum 2011, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 16-17, 2011.

182. Trivedi, A, Vaddady, P, Bhatacharjee, H, Lee, RE, **Meibohm, B**. Solubilizing formulations as an approach to increase the oral bioavailability of novel nitrofuranylamide drug candidates for the treatment of tuberculosis.
Presented at PharmForum 2011, the AAPS Southern Regional Discussion Group Annual Meeting, Memphis, TN, May 16-17, 2011.

183. Rakesh, Bruhn, D, **Meibohm, B**, Madhura, D, McNeil, MM, Scherman, M, Lee, RE. Nitrofuranyl isoxazolines as anti tuberculosis agents.

Presented at 33rd National Medicinal Chemistry Symposium, Tucson, AZ, May 20-23, 2012.

184. Parker, RB, **Meibohm, B**, Hu, Z, Laizure, SC. Ethanol inhibits the metabolism of oseltamivir to its active metabolite.
Presented at the ACCP Annual Meeting, American College of Clinical Pharmacy, Hollywood, FL, October 21-24. 2012.

185. Thomson, MMS, Krauel, S, Hines, RN, Schuetz, EG, **Meibohm, B**. Lack of Effect of Genetic Variants on the Age-Associated Protein Expression of OATP1B1 and OATP1B3 in Human Pediatric Liver.

Encore presentation at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Indianapolis, IN, March 5-9, 2013.

186. Rathi C, Robinson GT, Schermann M, Liu J, Lee RE, Lenaerts AJ, **Meibohm B**. Dose-Exposure Response Analysis of Spectinamide Antibiotic Lee 1810 in Mycobacterium tuberculosis Infected Mice. Poster number: 07T0130

Encore presentation at the New York Academy of Sciences/PepsiCo Journey through Science Day, World Trade Center, New York City, NY, 2016.

187. Wagh S, Rathi C, Robertson GT, Liu J, Ryman JT, Scherman MS, Lee RE, Lenaerts AJ, **Meibohm B**. Exposure-Response Analysis of Lee 1810, a Lead Spectinamide Antibiotic in Mycobacterium tuberculosis Infected Mice.

Presented at the International Workshop on Clinical Pharmacology of Tuberculosis Drugs, Atlanta, GA, October 15, 2017

188. Gonzalez-Juarrero M, Lukka P, Wagh S, Rathi C, Arab J, Durham P, Lenaerts A, Lee R, Hickey A, **Meibohm B**. Aerosol Spectinamide-1599 Therapy Against Tuberculosis.

Presented at the 4th International Inhaled Therapies for TB Meeting, Durham, NC, October 16-17, 2017.

189. Wagh S, Rathi C, Lukka PB, Parmar K, Temrikar Z, Liu J, Scherman MS, Lee RE, Robertson GT, Lenaerts AJ, **Meibohm B**. PK/PD Modeling of Spectinamide 1599 in Mycobacterium tuberculosis Infected Mice.

Presented at the 2018 Drug Discovery & Development Colloquium, Lexington, KY, June 21-23, 2018.

190. **Meibohm, B**, Lukka, PB, Wagh, S, Ryman, JT, Arab, J, Parmar K, Temrikar Z, Lee, RE, Braunstein M, Hickey AJ, Gonzalez-Juarrero, M. Pharmacokinetics and Tissue Distribution of Spectinamide 1599 after Intrapulmonary Aerosol Administration in Mice.
Presented at Gordon Research Conference on Tuberculosis Drug Discovery & Development, July 7-12, 2019, Castelldefels, Spain.

191. Lukka PB, Woods M, Chhim R, Phelps SJ, Wheless JW, **Meibohm B**. Pediatric Clinical PK of Lacosamide: Identification of Interacting Antiepileptic Drugs and Optimal Dosing Regimens.

Presented at 17th International Conference in Therapeutic Drug Monitoring & Clinical Toxicology, Foz do Iguaçu, Brazil, September 22-26, 2019.

192. Sullivan G, Kiu R, **Meibohm B**, Lederman S. Pharmacokinetic Results of a Dose Proportionality and Food Effect Study of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL).

Presented at the American Society of Clinical Psychopharmacology Annual Meeting (virtual), May 29-30, 2020.

193. Sullivan G, Fogarty S, Kiu R, **Meibohm B**, Lederman S. Phase 1 Pharmacokinetic Study of a Once-Daily Formulation of TNX-601 CR (Tianeptine Oxalate Controlled-Release) Tablets.

Presented at the American Society of Clinical Psychopharmacology Annual Meeting (virtual), May 29-30, 2020.

194. Ali Z, Walz A, Pearce C, Lee RE, Robertson GT, Hickey AJ, **Meibohm B**, Gonzalez-Juarrero M. Preclinical in vivo assessment of replacing linezolid for inhaled spectinamide 1599 in the Nix-TB regimen.

Presented at 52nd Union World Conference on Lung Health (virtual), October 19-22, 2021.

195. Yang, B, Temrikar, ZH, Srivastava, A, **Meibohm B**, Laizure, SC, Parker, RB. Ethanol Inhibits the Metabolism of the Multiple Sclerosis Drug Dimethyl Fumarate to its Active Metabolite and Decreases Brain Exposure.

Presented at Experimental Biology 2022, Philadelphia, PA, April 2-5, 2022.

196. Ali Z, Dutt TS, Walz A, Pearce C, MacNeill A, Lee RE, Robertson GT, Hickey AJ, **Meibohm B**, Gonzalez-Juarrero M. Preclinical in vivo evaluation of modified Nix-TB regimen.

Presented at Immunology 2022, American Association of Immunologists, Portland, OR, May 6-10, 2022.

197. Jonsson CB, Yang D, Golden JE, **Meibohm B**, Chung DH, Julander JG. Prophylactic and therapeutic efficacy of a novel brain-penetrant antiviral in lethal mouse models of Venezuelan and eastern equine encephalitis.

Presented at International Conference on Antiviral Research, Lyon, France, March 13-17, 2023.

198. Gonzalez-Juarrero M, Lee RE, Robertson GT, Hickey AJ, **Meibohm B**. Preclinical in vivo evaluation of a modified BPaL regimen replacing Linezolid with inhaled Spectinamides Lee 1599 (BPaS regimen).
Presented at Gordon Research Conference on Tuberculosis Drug Discovery & Development, July 24-28, 2023, Castelldefels, Spain.

199. Liu J, Robertson GT, Gonzalez-Juarrero M, **Meibohm B**, Lee RE. Hybrid antibiotics for M. tuberculosis.
Presented at Gordon Research Conference on Tuberculosis Drug Discovery & Development, July 24-28, 2023, Castelldefels, Spain.

200. Temrikar ZH, Panetta JC, Lyons MA, Lee RE, Robertson GT, Hickey AJ, Gonzalez-Juarrero M, **Meibohm B**. Preclinical PK/PD Modeling Meta-Analysis Framework to Evaluate Combination Partners for Spectinamide Anti-Tuberculosis Agents.
Presented at Gordon Research Conference on Tuberculosis Drug Discovery & Development, July 24-28, 2023, Castelldefels, Spain.

Appendix B

Exhibit No.	Description
IPR2023-00481 EX1001	U.S. Patent No. 8,377,903 (De Luca, G., et al., "Cladribine Regimen for Treating Multiple Sclerosis," U.S. Patent No. 8,377,903 B2 (filed April 23, 2010; issued February 19, 2013)
IPR2023-00480 EX1001	U.S. Patent No. 7,713,947 (De Luca, G., et al., "Cladribine Regimen for Treating Multiple Sclerosis," U.S. Patent No. 7,713,947 B2 (filed June 18, 2007; issued May 11, 2010)
IPR2023-00480, Paper 2	IPR2023-00480 Paper 2 Petition for Inter Partes Review, U.S. Patent No. 7,713,947
IPR2023-00481, Paper 2	IPR2023-00481 Paper 2 Petition for Inter Partes Review, U.S. Patent No. 8,377,903
IPR2023-00480, Paper 8	IPR2023-00480 Patent Owner Preliminary Response
IPR2023-00481, Paper 8	IPR2023-00481 Patent Owner Preliminary Response
IPR2023-00480 EX1002	Declaration of Aaron Miller, MD
IPR2023-00481 EX1002	Declaration of Aaron Miller, MD
IPR2023-00480, Paper 10	IPR2023-00480 Institution Decision
IPR2023-00481, Paper 10	IPR2023-00481 Institution Decision
IPR2023-00480 and IPR2023-00481, EX1013	Stelmasiak, Z., et al., "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," *Medical Science Monitor*, 4(1):4-8 (1998)

IPR2023-00480 and IPR2023-00481, EX1022	Bodor, N. and Dandiker, Y., "Oral Formulations of Cladribine," International Publication No. WO 2004/087101 A2 (filed March 26, 2004; published October 14, 2004)
IPR2023-00480 and IPR2023-00481, EX1048	Liliemark, J., "The Clinical Pharmacokinetics of Cladribine," *Clinical Pharmacokinetics*, 32(2):120-31 (1997)
IPR2023-00480 and IPR2023-00481, Ex. 2001	MAVENCLAD® Package Insert (September 2022)
IPR2023-00480 and IPR2023-00481, Ex. 2014	Betaseron® (Interferon beta- lb) Package Insert (1993)
IPR2023-00480 and IPR2023-00481, Ex. 2015	Avonex™ (Interferon Beta-1a) Package Insert (1996)
IPR2023-00480 and IPR2023-00481, Ex. 2016	Rebif® (Interferon Beta-1a) Package Insert (May 2003)
IPR2023-00480 and IPR2023-00481, Ex. 2017	Copaxone® (glatiramer acetate for injection) Package Insert (2014)
IPR2023-00480 and IPR2023-	Novantrone® (Mitoxantrone) Package Insert (Oct. 13, 2000)

00481, Ex. 2018	
IPR2023-00480 and IPR2023-00481, Ex. 2019	Tysabri® (natalizumab) Package Insert (Nov. 2004)
IPR2023-00480 and IPR2023-00481, Ex. 2043	J. Liliemark et al., *On the Bioavailability of Oral and Subcutaneous 2-Chloro-2'-Deoxydenosine in Humans: Alternative Routes of Administration*, 10 JOURNAL OF CLINICAL ONCOLOGY 1514 (1992)
IPR2023-00480 and IPR2023-00481, Ex. 2009	Miller Deposition Transcript (December 12, 2023)
IPR2023-00480 and IPR2023-00481, Ex. 2062	Hainer JW, Barrett JS, Assaid CA, Fossler MJ, Cox DS, Leathers T, Leese PT. *Dosing in heavy-weight/obese patients with the LMWH, tinzaparin: a pharmacodynamic study*. Thromb Haemost. 2002 May; 87(5):817-23. PMID: 12038783
IPR2023-00480 and IPR2023-00481, Ex. 2063	Meibohm, B, Evans, WE: Clinical Pharmacodynamics & Pharmacokinetics. In: Helms, RA, Quan, DJ: *Textbook of Therapeutics: Drug and Disease Management*, 8th Ed., Lippincott Williams Wilkins 2006, ISBN 0-7817-5734, p. 1-31