

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENE COMPANY PTY LTD,
Petitioner

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,
Patent Owner

Case IPR2024-00313
U.S. Patent No. RE47,045

DECLARATION OF LEONIDE SAAD, Ph.D.

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I, Leonide Saad, Ph.D., have personal knowledge of the facts stated herein and provide the following testimony:

I. Personal Background and Introduction

1. I am currently Chief Scientific Officer of Alkeus Pharmaceuticals, Inc. (“Alkeus”), a position I have held since July 1, 2024. I also co-founded Alkeus in 2010 and was its President and Chief Executive Officer until June 30, 2024.

2. I received my Ph.D. from Massachusetts Institute of Technology (MIT). The focus of my Ph.D. was tissue engineering and regenerative medicine. I also hold a Financial Technology certificate from MIT Sloan School of Management, an MS in Mechanical Engineering from MIT, and a BS and MS in Applied Mathematics from the University of Paris VI (Sorbonne University). Further, I am a graduate of Ecole Polytechnique, Paris, with a concentration in organic chemistry and physics.

3. I understand that the U.S. Patent and Trademark Office has instituted an Inter Partes Review, IPR2024-00313, involving U.S. Patent No. RE47,045 (“the ’045 patent”) assigned to Columbia University. I also understand that the real parties-in-interest in IPR2024-00313 are The Trustees of Columbia University in the City of New York, the owner of the ’045 patent, and Alkeus Pharmaceuticals, Inc., the exclusive licensee of the ’045 patent.

4. I understand that Columbia has submitted the following exhibits in the inter partes review proceedings:

- **TEASE-1**

- **EX2086:** Hendrik P Scholl, Syed Mahmood Shah, Christine Nichols Kay, Stephen H Tsang, Kimberly E Stepien, Paul S Bernstein, Byron L Lam, Michael B Gorin, Ilyas Washington, Leonide Saad. TEASE: a phase 2 clinical trial assessing the tolerability and effects of oral once-a-day ALK-001 on Stargardt disease. *Invest. Ophthalmol. Vis. Sci.* 2016;57(12):2685. (**Scholl 2016**)
- **EX2087:** Hendrik P Scholl, Stephen H Tsang, Christine Nichols Kay, Thomas B. Connor, Michael B Gorin, Paul S Bernstein, Byron L Lam, Zach Strecker, Justin Tyler Zaremba, Gabrielle DeBartolomeo, Ilyas Washington, Leonide Saad. Stargardt disease ALK-001 phase 2 clinical trial: 12-month interim data. *Invest. Ophthalmol. Vis. Sci.* 2019;60(9):1336. (**Scholl 2019**)
- **EX2088:** Hendrik P Scholl, Gabrielle DeBartolomeo, Ilyas Washington, Leonide Saad. ALK-001 (C20-D3-Vitamin A) slows the growth of atrophic lesions in *ABCA4*-related Stargardt Disease: Results of a Phase 2 placebo-controlled clinical trial (TEASE study). *Invest. Ophthalmol. Vis. Sci.* 2022;63(7):38. (**Scholl 2022**)
- **EX2089:** Christine Nichols Kay, Hendrik P Scholl, Leonide Saad. ALK-001 (C20-D3-Vitamin A) Slows the Growth of Atrophic Lesions in *ABCA4*-related Stargardt Disease: Results of a Randomized Placebo-Controlled Clinical Trial (TEASE study). American Academy of Ophthalmology 2022 Meeting Abstract No. 30069593. (**Kay 2022**)
- **EX2090:** Hendrik P Scholl, Leonide Saad, Gabrielle DeBartolomeo, Neil M Bressler, Stephen H Tsang, Kimberly E Stepien, Paul S Bernstein, Byron L Lam, Michael B Gorin, Ilyas Washington, Christine Nichols Kay. Gildeuretinol

Enables the Vitamin A Cycle. *Invest. Ophthalmol. Vis. Sci.* 2024;65(7):6438. (Scholl 2024)

- **TEASE-3**

- **EX2091:** Michael B Gorin, Leonide Saad, Gabrielle DeBartolomeo, Ilyas Washington, Hendrik P Scholl, Marc T. Mathias, Philip Ferrone, Christine Nichols Kay. Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study. *Invest. Ophthalmol. Vis. Sci.* 2024;65(7):3310. (Gorin 2024)
- **EX2092:** Alkeus Press Release, “Alkeus Pharmaceuticals Announces Presentation of a TEASE-3 Study Update Showing Progression Stalled in Early-Stage Stargardt Disease Patients Treated with Gildeuretinol,” July 18, 2024. (2024.07.18 Alkeus Press Release)
- **EX2093:** Alkeus Press Release, “Alkeus Pharmaceuticals Presents Positive Interim Data Showing Gildeuretinol Halted Stargardt Disease Progression,” January 10, 2024. (2024.01.10 Alkeus Press Release)

- **SAGA**

- **EX2094:** Boyer DS, Saad L, Washington I, Melamud A, Graham KB, O’Malley AE, DeBartolomeo GM, Jiang H, Harris LD, Kay CN, Ferrone PJ, Khan S. Gildeuretinol in Geographic Atrophy: Results from SAGA, a 2-year, Randomized, Double-masked, Placebo-controlled Study. American Academy of Ophthalmology 2024 Meeting. (Boyer 2024)
- **EX2095:** Alkeus Press Release, “Alkeus Pharmaceuticals Announces Results from the SAGA Study of Oral Gildeuretinol in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration,” September 17, 2024. (2024.09.17 Alkeus Press Release)

- **Press Releases**

- **EX2096:** Alkeus Press Release, “FDA Grants Alkeus Pharmaceuticals Breakthrough Therapy Designation for ALK-

001 (C20-D3-vitamin A) for the Treatment of Stargardt Disease,” July 14, 2021. **(2021.07.14 Alkeus Press Release)**

- **EX2097:** Alkeus Press Release, “Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease,” June 5, 2023. **(2023.06.05 Alkeus Press Release)**

5. I provide this declaration based on my personal knowledge and my role in the study to investigate the Tolerability and Effects of ALK-001 on Stargardt Disease (“TEASE”) and in the Study of ALK-001 in Geographic Atrophy (“SAGA”). Specifically, I have been asked to address each of these exhibits and how the results they disclose were generated from the TEASE-1, TEASE-3, and SAGA clinical studies.

6. Further, I provide this declaration based on my personal knowledge and my role as co-founder of Alkeus, my current role as Chief Scientific Officer of Alkeus, and my previous role as President and Chief Executive Officer of Alkeus. As a member of the Leadership Team at Alkeus, I was involved in preparing press releases and submitting them to news wires for their release to the public. Press releases were issued to disseminate information to the public about Alkeus, including ongoing business and commercial progress.

II. Alkeus’s TEASE and SAGA Studies

7. Alkeus is a biopharmaceutical company currently located in Cambridge, Massachusetts. I co-founded Alkeus in 2010 together with Ilyas

Washington, Ph.D., the inventor of the '045 patent. Since Alkeus's founding, we have been working to develop therapies for serious diseases of the eye with high unmet medical need. These diseases include geographic atrophy (GA) secondary to age-related macular degeneration (AMD), and Stargardt disease.

8. Alkeus's breakthrough-designated lead candidate, ALK-001 (gildeuretinol acetate, or C20-deuterated-retinyl acetate), is currently being used in clinical trials for the treatment of Stargardt disease and for geographic atrophy (GA) secondary to age-related macular degeneration (AMD). In particular, our trials include the TEASE trials (NCT02402660¹) for Stargardt disease and the SAGA study for AMD (NCT03845582²).

9. The TEASE trials consist of four clinical studies of ALK-001 in Stargardt disease, denoted as TEASE-1, TEASE-2, TEASE-3, and TEASE-4.

- TEASE-1 was a randomized, double-masked, placebo-controlled trial in 50 patients with Stargardt disease and is now completed.
- TEASE-2 is an ongoing, fully enrolled, randomized, double-masked, placebo-controlled trial in 80 patients with Stargardt disease.
- TEASE-3 is an ongoing, open-label study designed to assess ALK-001 in early-stage Stargardt patients.

¹ The TEASE study is further described at ClinicalTrials.Gov (<https://clinicaltrials.gov/study/NCT02402660>; EX2098), which provides, among other things, the study overview, participation criteria, and study plan.

² The SAGA study is also further described at ClinicalTrials.Gov (<https://clinicaltrials.gov/study/NCT03845582>; EX2099), which provides, among other things, the study overview, participation criteria, and study plan.

- TEASE-4 is an ongoing, open-label extension study of NCT02402660.

10. Columbia's Exhibit EX2097 (2023.06.05 Alkeus Press Release) is an Alkeus press release accurately disclosing that Alkeus is working towards the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) as rapidly as possible. I was involved in preparing this press release and submitting it to a news wire for its release to the public.

11. Columbia's Exhibits EX2086 (Scholl 2016), EX2087 (Scholl 2019), EX2088 (Scholl 2022), EX2089 (Kay 2022), and EX2090 (Scholl 2024) relate to Alkeus's TEASE-1 study. Columbia's Exhibits EX2091 (Gorin 2024), EX2092 (2024.07.18 Alkeus Press Release), and EX2093 (2024.01.10 Alkeus Press Release) relate to Alkeus's TEASE-3 study.

12. In addition to the TEASE trials, the SAGA study of ALK-001 was a 24-month, double-masked, randomized, placebo-controlled trial in approximately 200 patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Topline data will be presented at the American Academy of Ophthalmology's annual meeting in October 2024. Columbia's Exhibits EX2094 (Boyer 2024), and EX2095 (2024.09.17 Alkeus Press Release) relate to Alkeus's SAGA study.

A. Clinical Development of ALK-001

13. During my 14-year tenure at Alkeus, I have pioneered and led the development of ALK-001 for Stargardt disease and age-related macular degeneration. ALK-001 is a formulation of C₂₀-D₃ vitamin A, more specifically C₂₀-deuterated-retinyl acetate, also known as gildeuretinol acetate.

14. I am the study director for both the TEASE trials (NCT02402660) and the SAGA trial (NCT03845582). As the study director, I have been responsible for the TEASE and SAGA studies, including designing the protocols, overseeing the studies, assessing and reporting the results, and drawing conclusions from the studies. As such, I have first-hand knowledge of how the clinical trials were performed, the data generated from the clinical trials, and the information related thereto disclosed in EX2086 (Scholl 2016), EX2087 (Scholl 2019), EX2088 (Scholl 2022), EX2089 (Kay 2022), EX2090 (Scholl 2024), EX2091 (Gorin 2024), EX2092 (2024.07.18 Alkeus Press Release), EX2093 (2024.01.10 Alkeus Press Release), EX2094 (Boyer 2024), and EX2095 (2024.09.17 Alkeus Press Release).

B. Exhibits Related to the TEASE-1 Trial

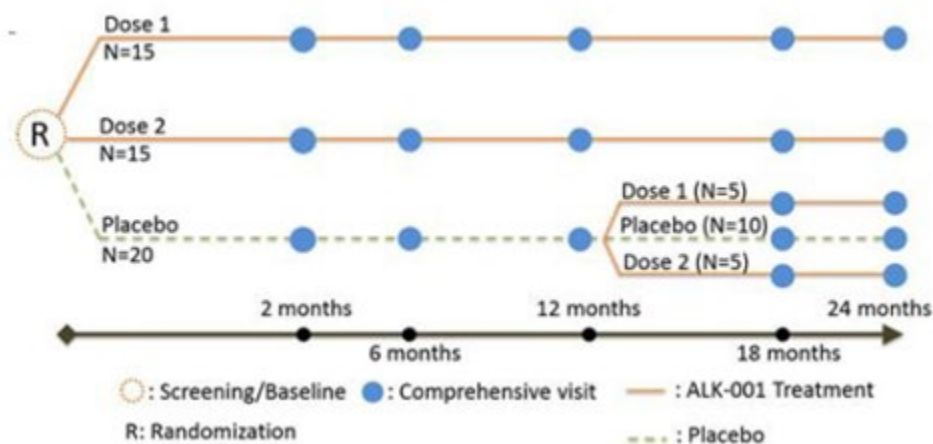
15. As described above, I am the study director for the TEASE trials, including TEASE-1. Exhibits EX2086 (Scholl 2016), EX2087 (Scholl 2019), EX2088 (Scholl 2022), EX2089 (Kay 2022), and EX2090 (Scholl 2024) are abstracts accurately disclosing the methods and results of the TEASE-1 trial.

16. As study director, I was involved in designing the trial protocol and statistical analyses for the TEASE-1 trial. I was also involved in overseeing the conduct of the study. The TEASE-1 trial was conducted in accordance with the principles of the Declaration of Helsinki, International Conference on Harmonization E6 Good Clinical Practice Consolidated Guideline, and other relevant regulations.

1. Study Design

17. The TEASE-1 study was a 24-month, multicenter, double-masked, placebo-controlled trial to evaluate the efficacy and safety of daily oral ALK-001 (gildeuretinol acetate) in slowing the growth of atrophic retinal lesions in individuals with Stargardt disease. The trial was conducted at seven sites in the United States. EX2087 (Scholl 2019) at 1.

18. The study design is illustrated in the figure below:



EX2086 (Scholl 2016) at 2.

19. Participants were randomized in a 1.5:1.5:1:1 ratio to receive gildeuretinol acetate 14 mg capsules, gildeuretinol acetate 24 mg capsules, placebo capsules, or to a crossover cohort initially taking placebo capsules. *Id.* After one year, participants in the crossover cohort, randomly crossed over in a 1:1 ratio, from placebo to gildeuretinol acetate 14 mg capsules or gildeuretinol acetate 24 mg capsules, for the second year of the trial. *Id.*

20. Gildeuretinol acetate and placebo capsules were identically appearing capsules. Participants were instructed to consume three or fewer servings of vitamin A per day. Participants also were advised to avoid vitamin A-containing supplements and liver-based products. Fruits and vegetables that contain beta-carotene, not preformed vitamin A, could be consumed without limitation.

2. Study Endpoints

21. The prespecified primary efficacy endpoint was the growth rate of the square root area of well-delineated and homogenous areas of atrophic retinal lesions, as measured by retinal fundus autofluorescence imaging. EX2088 (Scholl 2022) at 1. Atrophic retinal lesions were measured in a masked fashion by two graders. Atrophic retinal lesions correspond to irreversible loss of visual function and can be objectively measured on digital retinal images.

22. As recognized in the literature, lesion growth rate as determined by autofluorescence imaging is relevant to monitoring disease progression in Stargardt's patients:

- Rupert W. Strauss et al. ProgStar Study Group. Progression of Stargardt Disease as Determined by Fundus Autofluorescence Over a 12-Month Period: ProgStar Report No. 11. *JAMA Ophthalmol.* 2019 Oct. 1;137(10):1134-1145 (EX2100).

23. Best-corrected visual acuity (BCVA) as assessed by total letter score on ETDRS charts was a secondary endpoint.

24. Safety was evaluated through treatment-emergent adverse events, serious adverse events, 12-lead electrocardiogram, vital signs, physical and ocular exams, and laboratory tests, including liver function tests. Blood was collected at each visit to measure giledeuretinol acetate's pharmacokinetics and for laboratory testing, including liver function tests and plasma retinol measurements.

25. Mean change from baseline at 8 weeks in dark-adaptation parameters was evaluated. EX2090 (Scholl 2024) at 1. During 60 minutes of dark adaptation, dark adaptation was measured by full-field, psychophysical dark-adaptation testing acquired on an Espion 3. *Id.* at 1-2. In addition, a six-question dark-adaptation questionnaire was administered at baseline and week 8. *Id.*

3. Statistical Analysis

26. Analysis of data from the TEASE-1 study was performed by external statisticians as is common practice in the pharmaceutical industry. I was involved

in reviewing the data analyses performed and developing conclusions about the clinical study results.

27. The primary endpoint analysis used a linear mixed-effect model (LMEM) with repeated measures and a variety of fixed and random effects.

EX2088 (Scholl 2022) at 1. All observed data, including both eyes, were utilized.

28. The following dark adaption parameters were measured: cone threshold, cone coefficient, cone time constant, second rod recovery rate, cone rod breakpoint, third rod recovery rate, and rod-rod breakpoint. EX2090 (Scholl 2024) at 2. The p-value was determined from a two-sample t-test with unequal variances. *Id.*

29. Clinical trial participants, clinical investigators, and all employees of Alkeus (myself included) remained blinded throughout the course of the clinical studies. In other words, we were kept unaware of which treatment arms participants had been assigned to. Study blinding was preserved until the data analyses were completed and conclusions about the results of the TEASE-1 study had been drawn.

C. Exhibits Relating to the TEASE-3 Study

30. As described above, I am the study director for the TEASE trials, including TEASE-3. Exhibit EX2091 (Gorin 2024) is an abstract accurately disclosing the methods and results of the TEASE-3 trial. Exhibits EX2092

(2024.07.18 Alkeus Press Release) and EX2093 (2024.01.10 Alkeus Press Release) are Alkeus press releases accurately disclosing the methods and results of the TEASE-3 trial.

31. As study director, I was involved in designing the trial protocol and statistical analyses for the TEASE-3 trial. I was also involved in overseeing the conduct of the study. The TEASE-3 trial was conducted in accordance with the principles of the Declaration of Helsinki, International Conference on Harmonization E6 Good Clinical Practice Consolidated Guideline, and other relevant regulations.

1. Study Design

32. The TEASE-3 study is an open-label, multicenter, case-control study evaluating disease progression in early-stage patients treated with ALK-001 (gildeuretinol acetate), in comparison to their symptomatic siblings when untreated and at the same age. EX2091 (Gorin 2024) at 2. The trial is ongoing and conducted at multiple sites in the United States.

33. The first three participants are three patients (aged 13, 17, and 18) each with two pathogenic *ABCA4* mutations, exhibiting early signs of maculopathy, but with 20/20 visual acuity and no complaints of visual impairment, and each with a two-year-older symptomatic sibling with Stargardt disease. *Id.* Patients took one gildeuretinol acetate 14 mg capsule daily for 2 to 4 years. *Id.*

34. Similar to TEASE-1, participants were instructed to consume three or fewer servings of vitamin A per day and advised to avoid vitamin A-containing supplements and liver-based products. Fruits and vegetables that contain beta-carotene, not preformed vitamin A, could be consumed without limitation.

2. Study Endpoints

35. Disease development was monitored by best-corrected visual acuity (BCVA), fundus autofluorescence (FAF) imaging, photoreceptor density by OCT, and retinal sensitivity by microperimetry.

36. As recognized in the literature, these outcomes are relevant to monitoring disease progression in Stargardt's patients:

- Avery E. Sears et al. Towards Treatment of Stargardt Disease: Workshop Organized and Sponsored by the Foundation Fighting Blindness. *Transl. Vis. Sci. Tech.* 2017 Sept. 14;6(5):6 (EX2101).

3. Statistical Analysis

37. In provisional analyses, measurements from the left and right eye for each participant were averaged for each visit to produce a single statistical unit for both eyes. Measurements were then compared to the participant's untreated symptomatic siblings when at the same age. EX2091 (Gorin 2024) at 2.

38. With the open-label design, we were able to perform statistical analyses in-house. I was involved in performing these analyses, reviewing the data and developing conclusions about the clinical study results.

D. Exhibits Relating to the SAGA Trial

39. As described above, I am the study director for the SAGA trial.

Exhibit EX2094 (Boyer 2024) is an abstract accurately disclosing the methods and results of the SAGA trial. Exhibit EX2095 (2024.09.17 Alkeus Press Release) is an Alkeus press release accurately disclosing the methods and results of the SAGA trial.

40. As study director, I was involved in designing the trial protocol and the statistical analysis plan for the SAGA trial. I was also involved in overseeing the conduct of the study. The SAGA trial was conducted in accordance with the principles of the Declaration of Helsinki, International Conference on Harmonization E6 Good Clinical Practice Consolidated Guideline, and other relevant regulations.

1. Study Design

41. The SAGA study was a 24-month, double-masked, randomized, placebo-controlled trial of oral ALK-001 (gildeuretinol acetate) in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). EX2094 (Boyer 2024). The study investigated the safety, pharmacokinetics, tolerability, and efficacy of ALK-001. *Id.*

42. A total of 198 patients were enrolled in the study. EX2095 (2024.09.17 Alkeus Press Release) at 1. Participants with geographic atrophy (GA)

secondary to AMD in at least one eye were randomized 2:1 to gildeuretinol 14 mg/day:placebo. EX2094 (Boyer 2024).

43. Gildeuretinol acetate and placebo capsules were identically appearing capsules. Participants were advised to avoid vitamin A-containing supplements and liver-based products. Fruits and vegetables contain beta-carotene, not preformed vitamin A, and could be consumed without limitation.

2. Study Endpoints

44. The primary efficacy endpoint was the growth rate of GA lesions from baseline to 24 months as assessed by fundus autofluorescence (FAF). The first key secondary endpoint was the change in low luminance visual acuity (LLVA) at 24 months.

45. GA lesions represent expanding regions of dead retina and are an objective measure of disease progression as they can be readily measured using digital retinal imaging techniques standard in the field.

46. LLVA is recognized in the literature as a functional measure of AMD progression. *See* Kimberly J. Cocce et al. Visual function metrics in early and intermediate dry age-related macular degeneration for use as clinical trial endpoints. *Am. J. Ophthalmol.* 2018 May;189:127-138 (EX2102).

3. Statistical Analysis

47. Analysis of data from the SAGA study was performed by external statisticians as is common practice in the pharmaceutical industry. I was involved in reviewing the data analyses performed and developing conclusions about the clinical study results.

48. Similar to TEASE-1, the primary endpoint analysis used a linear mixed-effect model (LMEM) with repeated measures and a variety of fixed and random effects. The growth rate of GA lesions was analyzed and compared between patients taking placebo and those taking ALK-001. All observed data, including both eyes, were utilized.

49. Clinical trial participants, clinical investigators, and all employees of Alkeus (myself included) remained blinded throughout the course of the clinical studies. In other words, we were kept unaware of which treatment arms participants had been assigned to. Study blinding was preserved until the data analyses were completed and conclusions about the results of the SAGA study had been drawn.

III. Breakthrough Designation of ALK-001

50. ALK-001 has received breakthrough therapy designation for the treatment of Stargardt disease, as well as orphan drug designation from the U.S. Food and Drug Administration.

51. Columbia's Exhibit EX2096 (2021.07.14 Alkeus Press Release)

relates to and accurately describes the FDA's grant of Breakthrough Therapy Designation to ALK-001 for the treatment of Stargardt Disease. I was involved in preparing this press release and in submitting it to a news wire for its release to the public.

IV. The TEASE Trial Exhibits, the SAGA Trial Exhibits, and the Alkeus Press Release Exhibits Are Records of Regularly Conducted Activity by Alkeus

52. Based on my involvement with the TEASE and SAGA clinical trials, I have first-hand knowledge of how these test data disclosed were generated.

53. The TEASE trial exhibits (i.e., EX2086 (Scholl 2016), EX2087 (Scholl 2019), EX2088 (Scholl 2022), EX2089 (Kay 2022), EX2090 (Scholl 2024), EX2091 (Gorin 2024), EX2092 (2024.07.18 Alkeus Press Release), EX2093 (2024.01.10 Alkeus Press Release) and SAGA trial exhibits (i.e., EX2094 (Boyer 2024), EX2095 (2024.09.17 Alkeus Press Release)) are records of regularly conducted activity by Alkeus. Working with the clinical investigators conducting the trials on behalf of Alkeus, each of the above documents was prepared as part of Alkeus's regularly conducted business whereby we document and publicize results from our clinical trials. For example, the abstracts are relied upon in our press releases and on our website to inform the public regarding our work and Alkeus's business progress.

54. The Alkeus press release exhibits (i.e., EX2096 (2021.07.14 Alkeus Press Release), EX2097 (2023.06.05 Alkeus Press Release)) are also records of regularly conducted activity by Alkeus. As discussed above, press releases are used in Alkeus's business to disseminate material information to the public about, for example, ongoing business and commercial progress.

55. I am a co-author of each abstract and was personally involved in their preparation and am familiar with how they are retained by Alkeus. I was also personally involved in preparing and submitting each press release and am familiar with how they are retained by Alkeus. Specifically, the TEASE trial exhibits, SAGA trial exhibits, and Alkeus press release exhibits:

(A) were made or obtained at or near the time of occurrence of the matters set forth in the records, by, or from information transmitted by, a person with personal knowledge of those matters;

(B) were kept in the course of regularly conducted business activity;

(C) were created or obtained as a regular business practice; and

(D) are the types of information created, obtained, and used in the ordinary course of business.

V. Conclusion

56. 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 willful 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: September 22, 2024

By: /Leonide C. Saad/

Leonide Saad, Ph.D.