

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEUROCRINE BIOSCIENCES, INC.
Petitioner

v.

SPRUCE BIOSCIENCES, INC.
Patent Owner

U.S. Patent 12,569,491 B2

DECLARATION OF JUNE ANN MUNFORD

IN SUPPORT OF PETITION FOR POST GRANT REVIEW OF U.S.
PATENT NO. 12,569,491 B2

1. My name is June Ann Munford. I am over the age of 18, have personal knowledge of the facts set forth herein, and am competent to testify to the same.
2. I earned a Master of Library and Information Science (MLIS) from the University of Wisconsin-Milwaukee in 2009. I have over ten years of experience in the library/information science field. Beginning in 2004, I have served in various positions in the public library sector including Assistant Librarian, Youth Services Librarian and Library Director. I have attached my Curriculum Vitae as Appendix CV.
3. During my career in the library profession, I have been responsible for materials acquisition for multiple libraries. In that position, I have cataloged, purchased and processed incoming library works. That includes purchasing materials directly from vendors, recording publishing data from the material in question, creating detailed material records for library catalogs and physically preparing that material for circulation. In addition to my experience in acquisitions, I was also responsible for analyzing large collections of library materials, tailoring library records for optimal catalog

search performance and creating lending agreements between libraries during my time as a Library Director.

4. I am also familiar with the Internet Archive, a digital online library accessible and available to the general public. The Internet Archive, a 501(c)(3) non-profit and founded in 1996, is a publicly available digital library of Internet sites and other cultural artifacts that can be searched and accessed in digital form. Its mission is to provide universal access to all knowledge including books, films, magazines, websites, videos, software programs, audio recordings, and television. Like a physical library, it provides free access to everyone. The Internet Archive is available here: <https://archive.org/>.
5. The Internet Archive created a resource known as the “Wayback Machine” (<https://web.archive.org/>). The Wayback Machine makes it possible to search and browse more than 450 billion publicly available web pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search the Archive by keyword or a website URL. If archived records for a URL or the keywords are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates and be

taken to the collection of web captures associated with the specific web crawl and point in time the capture came from.

6. This archived data made viewable by the Wayback Machine is obtained using web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.
7. The Internet Archive assigns a URL to all archived files within the Wayback Machine in the following format: `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]`. This is known as an “extended URL” format.
8. For example, the Internet Archive extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` denotes the URL for the record of the Internet Archive home page archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28).
9. I have reviewed Exhibit 1075: *A Study to Examine the Absorption of GSK561679 in Healthy Male Volunteers (“GSK Study”)* (03 July 2013)

10. Attached hereto as Appendix A is a screen capture of the Internet Archive Wayback Machine entry for <http://clinicaltrials.gov/ct2/show/NCT00539136>. I secured these screen captures myself from <https://web.archive.org/web/20130703193522/http://clinicaltrials.gov/ct2/show/NCT00539136>. This record was captured as of May 22, 2026.

11. Appendix A is an Internet Archive capture of *A Study to Examine the Absorption of GSK561679 in Healthy Male Volunteers (“GSK Study”) (03 July 2013)* as hosted on the clinicaltrials.gov website. In comparing Appendix A to Exhibit 1075, it is my determination that Exhibit 1075 is a true and correct copy of *A Study to Examine the Absorption of GSK561679 in Healthy Male Volunteers (“GSK Study”) (03 July 2013)* as hosted on the clinicaltrials.gov website. As the Internet Archive captured this file as of July 3, 2013, it is my determination that *A Study to Examine the Absorption of GSK561679 in Healthy Male Volunteers (“GSK Study”) (03 July 2013)* was publicly available at least by July 3, 2013, via the Internet Archive.

12. I have been retained on behalf of the Petitioner to provide assistance in the above-illustrated matter in establishing the authenticity and public availability of the document discussed in this declaration. I am being compensated for my services in this matter at the rate of \$200.00 per hour

plus reasonable expenses. My statements are objective, and my compensation does not depend on the outcome of this matter.

13. I declare under penalty of perjury that the foregoing is true and correct. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further 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: 05/22/2026

A handwritten signature in black ink, appearing to read 'June Ann Munford', with a stylized, flowing script.

June Ann Munford

APPENDIX CV

June A. Munford
Curriculum Vitae

Education

University of Wisconsin-Milwaukee - MS, Library & Information Science, 2009
Milwaukee, WI

- Coursework included cataloging, metadata, data analysis, library systems, management strategies and collection development.
- Specialized in library advocacy, cataloging and public administration.

Grand Valley State University - BA, English Language & Literature, 2008
Allendale, MI

- Coursework included linguistics, documentation and literary analysis.
- Minor in political science with a focus in local-level economics and government.

Professional Experience

Researcher / Expert Witness, October 2017 – present
Freelance ● Pittsburgh, Pennsylvania & Grand Rapids, Michigan

- Material authentication and public accessibility determination. Declarations of authenticity and/or public accessibility provided upon research completion. Experienced with appeals and deposition process.
- Research provided on topics of public library operations, material publication history, digital database services and legacy web resources.
- Past clients include Alston & Bird, Arnold & Porter, Baker Botts, Fish & Richardson, Erise IP, Irell & Manella, O'Melveny & Myers, Perkins-Coie, Pillsbury Winthrop Shaw Pittman and Slayden Grubert Beard.

Library Director, February 2013 - March 2015
Dowagiac District Library ● Dowagiac, Michigan

- Executive administrator of the Dowagiac District Library. Located in Southwest Michigan, this library has a service area of 13,000, an annual operating budget of over \$400,000 and total assets of approximately \$1,300,000.

- Developed careful budgeting guidelines to produce a 15% surplus during the 2013-2014 & 2014-2015 fiscal years while being audited.
- Using this budget surplus, oversaw significant library investments including the purchase of property for a future building site, demolition of existing buildings and building renovation projects on the current facility.
- Led the organization and digitization of the library's archival records.
- Served as the public representative for the library, developing business relationships with local school, museum and tribal government entities.
- Developed an objective-based analysis system for measuring library services - including a full collection analysis of the library's 50,000+ circulating items and their records.

November 2010 - January 2013

Librarian & Branch Manager, Anchorage Public Library ● Anchorage, Alaska

- Headed the 2013 Anchorage Reads community reading campaign including event planning, staging public performances and creating marketing materials for mass distribution.
- Co-led the social media department of the library's marketing team, drafting social media guidelines, creating original content and instituting long-term planning via content calendars.
- Developed business relationships with The Boys & Girls Club, Anchorage School District and the US Army to establish summer reading programs for children.

June 2004 - September 2005, September 2006 - October 2013

Library Assistant, Hart Area Public Library
Hart, MI

- Responsible for verifying imported MARC records and original MARC cataloging for the local-level collection as well as the Michigan Electronic Library.
- Handled OCLC Worldcat interlibrary loan requests & fulfillment via ongoing communication with lending libraries.

Professional Involvement

Alaska Library Association - Anchorage Chapter

- Treasurer, 2012

Library Of Michigan

- Level VII Certification, 2008
- Level II Certification, 2013

Michigan Library Association Annual Conference 2014

- New Directors Conference Panel Member

Southwest Michigan Library Cooperative

- Represented the Dowagiac District Library, 2013-2015

Professional Development

Library Of Michigan Beginning Workshop, May 2008

Petoskey, MI

- Received training in cataloging, local history, collection management, children's literacy and reference service.

Public Library Association Intensive Library Management Training, October 2011

Nashville, TN

- Attended a five-day workshop focused on strategic planning, staff management, statistical analysis, collections and cataloging theory.

Alaska Library Association Annual Conference 2012 - Fairbanks, February 2012

Fairbanks, AK

- Attended seminars on EBSCO advanced search methods, budgeting, cataloging, database usage and marketing.

Depositions

2019 • Fish & Richardson

Apple v. Qualcomm (Case No. IPR2018-001281, 39521-00421IP, IPR2018-01282 and 39521-00421IP2)

2019 • Erise IP

Implicit, LLC v. Netscout Systems, Inc (Case No. 2:18-cv-53-JRG)

2019 • Perkins-Coie

Adobe Inc. v. RAH Color Technologies LLC (Case No. IPR2019-00627, IPR2019-00628, IPR2019-00629 and IPR2019-00646)

2020 ● O'Melveny & Myers

Maxell, Ltd. v. Apple Inc. (Case No. 5:19-cv-00036-RWS)

2021 ● Pillsbury Winthrop Shaw Pittman LLP

Intel v. SRC (Case No. IPR2020-1449)

2022 ● Perkins-Coie

Realtek v. Future Link (Case No. IPR2021-01182)

2023 ● Fish & Richardson

Neuroderm Ltd. v. Abbvie, Inc (Case No. PGR2022-00040)

2023 ● Fish & Richardson

Nearmap US Inc. v. Pictometry International Corp. (Case No. IPR2022-00735)

2023 ● Fish & Richardson

Samsung Electronics v. MemoryWeb LLC (Case No. 39843-0136PS1)

2023 ● Pillsbury Winthrop Shaw Whitman LLP

Gravel Rating Systems v. Costco Wholesale Corp. (Case No. 4:21-cv-149-ALM)

2024 ● Willkie-Farr

Netflix, Inc. v. VideoLabs. Inc. (Case No. IPR2023-00628)

2024 ● Quinn Emanuel Urquhart & Sullivan

Purdue University v. Wolfsped (Case No. 1:21-CV-840)

2024 ● Fish & Richardson

Dish Network v. Entropic Communications (Case No. IPR2024-00393)

2025 ● Perkins Coie

Amazon.com, Inc. v. Nokia Technologies Oy (Case No. IPR2024-00572)

2025 ● Fish & Richardson

Dish Network v. Entropic Communications (Case No. IPR2024-00373)

2025 ● Fish & Richardson

SK Nexilis Co., Ltd. v. Solus Advanced Materials (Case No. 2:2023-cv-00539)

2025 ● Covington & Burling

Samsung v. Pictiva (Case No. IPR2024-01222)

2026 ● Fish & Richardson

Shenzhen & Bambu Labsv. Stratasy (Case No. 2:24-cv-00644-JRG)

2026 ● Wilmer, Cutler, Pickering, Hale and Dorr

Shopify v. Lower48 (Case No. 6:22-cv-00997-DAE)

Limited Case and Clientele History

Alston & Bird

- Ericsson

v. Collision Communications (Case No. IPR2022-01233)

- Nokia

v. Neptune Subsea, Xtera (Case No. 1:17-cv-01876)

- Universal Electronics Inc

v. Roku Inc (Case No. IPR2022-00818)

Alavi & Anaipakos PLLC

- Stingray Group Inc. and Stingray Music USA, Inc.
v. Edwin A. Hernandez-Mondragon and Egla Corp. (Case No. 1:24-cv-21226-RAR)

Arnold & Porter

- Ivantis
v. Glaukos (Case No. 8:18-cv-00620)
- Samsung
v. Jawbone (Case No. 2:21-cv-00186)

Benesch Friedlander Coplan & Aronoff

- Voyis
v. Cathx (Case No. 5:21-cv-00077-RWS)

Buchanan, Ingersoll & Rooney PC

- Google LLC, AT&T Service Inc., T Mobile USA Inc., Cellco Partnership, Ericsson Inc. & Nokia of America Corp.
v. KT Corp & Pegasus Wireless Innovation LLC (Case No. IPR2025-00293)
- Google LLC
v. K. Mizra LLC (Case No. 1:25-cv-00236)

Covington & Burling

- First Solar, Inc.
v. JinkoSolar (Case No. 25-cv-223)

- Samsung
v. Pictiva (Case No. IPR2024-01222)

Deschert LLP

- Smaxtec Animal Care
v. ST Reproductive Technologies, LLC (Case No. IPR2024-00885)

Duane Morris

- Kangxi Communication Technologies
v. Skyworks Solutions Inc. (Case No. IPR2025-00373)
- Microsoft
v. Edge Networking Systems LLC (Case No. 1:24-cv-00215)

Erise I.P.

- Apple
v. Ericsson Inc. (Case No. IPR2022-00715)
v. Future Link Systems (Case No. IPRs 6317804, 6622108, 6807505, and 7917680)
v. INVT (Case No. 20-1881)
v. Navblazer LLC (Case No. IPR2020-01253)
v. Qualcomm (Case No. IPR2018-001281, 39521-00421IP, IPR2018-01282, 39521-00421IP2)
v. Quest Nettech Corp (Case No. 2:19-cv-00118-JRG)

- v. Telefonaktiebolaget LM Ericsson (Case No. IPR2022-00275)
- v. Theta IP, LLC (Case No. IPR2024-00818)
- v. THL Holding Company LLC (Case No. 1:23-cv-00548)

- CrowdStrike

- v. Skysong Innovations (Case No. IPR2025-01398)

- Fanduel

- v. CGT (Case No. 19-1393)

- Garmin

- v. Phillips North America LLC (Case No. 2:19-cv-6301-AB-KS)

- Netscout

- v. Longhorn HD LLC (Case No. 2:20-cv-00349)
 - v. Implicit, LLC (Case No. 2:18-cv-53-JRG)

- Sony Interactive Entertainment LLC

- v. Bot M8 LLC (Case No. IPR2020-01288)
 - v. Infernal Technology LLC (Case No. 2:19-CV-00248-JRG)

- Tesla

- v. Charge Fusion Technologies LLC (Case No. IPR2025-00032)

- Unified Patents

- v. GE Video Compression (Case No. 2:19-cv-248)

- Apple
 - v. AliveCor (Case No. 3:21-cv-03958)
 - v. LBS Innovations (Case No. 2:19-cv-00119-JRG-RSP)
 - v. Koss Corporation (Case No. IPR2021-00305)
 - v. Masimo (Case No. IPR 50095-0012IP1, 50095-0012IP2, 50095-0013IP1, 50095-0013IP2, 50095-0006IP1, 50095-0135IP1)
 - v. Neonode (Case No. 21-cv-08872-EMC)
 - v. Qualcomm (Case No. IPR2018-001281, 39521-00421IP, IPR2018-01282, 39521-00421IP2)
 - v. Resonant Sys. (Case No. 7:23-cv-00077-ADA)
- AsusTek Computer Inc.
 - v. Videolabs, Inc. (Case No. 22-CV-00720-ADA)
- Dell
 - v. Neo Wireless (Case No. IPR2022-00616)
- Dish Network
 - v. Entropic Communications, LLC (Case No. 2:2023-CV-01043)
 - v. Entropic Communications LLC (Case No. IPR2024-00393)
 - v. Realtime Adaptive Streaming (Case No. 1:17-CV-02097-RBJ)
 - v. TQ Delta LLC (Case No. 18-1798)
- Evapco Dry Cooling
 - v. SPG Dry Cooling (Case No. IPR2021-00688)
- Generac
 - v. PSLC (Case No. 2:24-cv-01270)
- Genetec

v. Sensormatic Electronics (Case No. 1:20-CV-00760)

- Huawei

v. Bell Northern Research LLC (Case No. IPR2019-01174)

- Kianxis

v. Blue Yonder (Case No. 3:20-cv-03636)

- LG Electronics

v. Bell Northern Research LLC (Case No. 3:18-cv-2864-CAB-BLM)

- MediaTek

v. MOSAID (Case No. IPR2024-00718)

- Metaswitch

v. Sonus Networks (Case No. IPR2018-01719)

- Microsoft

v. Throughput Inc (Case No. IPR2022-00757)

- Mom Enterprises

v. Ddrops Company (Case No. 1:22-cv-00332)

- MLC Intellectual Property

v. MicronTech (Case No. 3:14-cv-03657-SI)

- Nearmap Inc

v. EagleView Technologies (Case No. IPR2022-01009)

- Neuroderm Ltd.

v. Abbvie, Inc (Case No. PGR2022-00040)

- Par-Kan
 - v. Unverferth (Case No. 3:23-cv-00653)
- Posco Co Ltd.
 - v. Pascal Drillet et al. (Case No. IPR2025-00370)
- Realtek Semiconductor
 - v. Future Link (Case No. IPR2021-01182)
- Quectel
 - v. Koninklijke Philips (Case No. 1:20-cv-01710)
- Samsung
 - v. Aire Technology (Case No. IPR2022-00877)
 - v. Bell Northern Research (Case No. 2:19-cv-00286-JRG)
 - v. Communication Technologies Inc (Case No. IPR2022-01221)
 - v. Jawbone Innovations (Case No. IPR2022-00865)
 - v. MemoryWeb LLC (Case No. IPR2022-00885)
 - v. Dodots Licensing Solutions (Case No. IPR2023-00701)
 - v. Telefonaktiebolaget LM Ericsson (Case No. IPR2021-00615)
- Tesla
 - v. Intellectual Ventures (Case No. 1:24-cv-00390, 6:24-cv-00188)
- Texas Instruments
 - v. ParkerVision (Case No. IPR2024-00934)
 - v. Vantage Micro LLC (Case No. IPR2020-01261)

- Xilinx

v. Sentient Sensors LCC (Case No. 1:22-cv-00173)

Goodwin Proctor

- Intel

v. Proxense, LLC (Case No. 6:24-cv-00283)

- Samsung Electronics

v. Mobile Data Technologies (Case No. 2:24-cv-00435)

- Taiwan Semiconductor Manufacturing Company Ltd.

v. Advanced Integrated Circuit Process LLC (Case No. 2:24-cv-00623)

Groombridge Wu

- Atossa

v. Jina & Intas Pharmaceuticals (Case No. PGR2025-00043)

- Nearmap

v. Eagle View Technologies Inc. and Pictometry International Corp. (Case No. 2:21-cv-00283-TS-DAO)

Holland & Knight

- Wilmington Trust, N.A.

v. Herman Segal & John Hancock Life Insurance Company of New York (Case No. 1:21-CV-01540-PKC-TAM)

Irell & Manella

- Curium

Latham & Watkins LLP

- Apple

v. Advanced Coding Research LLC

- Google

v. Advanced Coding Research (Case No. 2:24-cv-0035)

- Western Digital Technologies

MR Technologies GmbH (Case No. 8:24-cv-01848-JVS)

Leydig, Voit & Mayer, Ltd.

- Public Availability Consultancy

O'Melveny & Myers

- Apple

v. Maxell (Case No. 5:19-cv-00036-RWS)

- Disney Media & Entertainment Distribution LLC

v. Digital Media Technology Holdings, LLC (Case No. 2:22-cv-01642)

- Micron Technology Inc.
v. Besang Inc (Case No. IPR2023-00900)
- Samsung
v. Daedalus Prime LLC (1335 Investigation)

Perkins-Coie

- Amazon
v. Nokia (Case No. IPR2024-00847 and IPR2024-00848)
v. Nokia Technologies Oy (Case No. IPR2024-00572)
- Google LLC
v. Clear Imaging Research LLC (Case No. 202510451)
- Heru Industries
v. The UAB Research Foundation (Case No. IPR2022-01148)
- Intel Corporation
v. BeSang Inc. (Case No. IPR2023-00991)
v. BitMICRO (Case No. 5:23-cv-00625)
v. Telefonaktiebolaget L M Ericsson (Case No. IPR2024-00610)
- Microsoft
v. Sandpiper (Case No. 2:25-cv-00664)
- Niantic, Inc.
v. ImagineAR, Inc. (C.A. No. 24-1252-JD)

- Realtek Semiconductor

v. Future Link (Case No. IPR2021-01182)

- r-pac

v. Adasa, Inc. (Case No. 1:2024cv06102)

- Twitter Inc

v. VOIP-Pal.com (Case No. 3:20-cv-02397-JD)

- Twitch/Amazon

v. RazDog (Case No. IPR2025-00308)

- TCL Industries

v. Koninklijke Philips NV (Case No. IPR2021-00495, IPR2021-00496 and IPR2021-00497)

- VusionGroup

v. Hanshow (Case No. IPR2024-00857)

Pillsbury Winthrop Shaw Pittman

- Intel

v. FG SRC LLC (Case No. 6:20-cv-00315)

- Gravel Rating Systems

v. Costco (Case No. 4:21-cv-149)

v. Lowe's Home Centers (Case No. 4:21-cv-150)

v. T-Mobile USA (Case No. 4:21-cv-152)

v. Kohl's Inc. (Case No. 4:21-cv-258)

v. Under Armor (Case No. 4:21-cv-356)

Quinn Emanuel

- Exact Sciences Corporation
 - v. Geneoscopy, Inc. (Case No. IPR2024-00459 and IPR2024-1330)

- ServiceNow, Inc.
 - v. InQuisient, Inc. (Case No. 22-900-CJB)

- Wolfspeed
 - v. The Trustees of Purdue University (Case No. 1:2021-cv-00840)

Sheppard, Mullin, Richter & Hampton LLP

- Advanced Micro Devices, Inc and Pensando Systems, Inc.
 - v. Concurrent Ventures LLC and Xtreamedge, Inc. (Case No. IPR2025-00478)

- Amazon
 - v. Nokia

- Cadence Design Systems Inc.
 - v. Semiconductor Design Technologies (Case No. 3:23-cv-01001)

- Marvell Semiconductor
 - v. Credo Technology (Case No. IPR2025-01219)

- Sandisk Technologies, Inc.
 - v. Longitude Flash Memory Solutions Ltd. (Case No. IPR2025-01283)

Shook, Hardy & Bacon LLP

- HP Inc.

v. Universal Connectivity Technologies (Case No. 1:23-cv-01177)

Stern, Kessler, Goldstein & Fox

- Preliminary Research

Wilmer, Cutler, Pickering, Hale and Dorr

- Apple

v. Shunock (Case No. 1:23-cv-08598)

- Dell Technologies Inc

v. EireOg Innovations Ltd. (Case No. 1:24-cv-00416-AD)

- Dropbox

- Quest Diagnostics Inc., Haystack Oncology Inc. and Haystack Oncology GmbH

v. Natera, Inc. (Case No. 1:23-cv-08598)

- NVIDIA

v. Onesta IP (Case No. 1:25-cv-00586)

- Oracle

v. EireOg Innovations Ltd. (Case No. 4-cv-00697-ADA)

- Roche Diabetes, Inc.
v. Trividia Health, Inc. (Case No. 1:24-cv-00668)
- Shopify Inc.
v. Lower48 IP LLC (C.A. No. 6:22-cv-00997-DAE)
- United Services Automobile Association
v. Regions Bank (Case No. 2-25-cv-00082)

Willkie, Farr & Gallagher LLP

- Lenovo, Dell, HP
v. Universal Connectivity Technologies Inc. (Case No. 2:2023cv00449)
- Neurent
v. The Foundry, LLC (Case No. IPR2024-00669)
- Netflix, Inc.
v. DivX (Case No. 2:19-cv-1602-GW-AGR)
- Netflix, Inc.
v. VideoLabs, Inc. (Case No. IPR2023-00628)

APPENDIX A

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

Search for studies:

Search

[Advanced Search](#) | [Help](#) | [Studies by Topic](#) | [Glossary](#)[Find Studies](#) | [About Clinical Studies](#) | [Submit Studies](#) | [Resources](#) | [About This Site](#)[Home](#) > [Find Studies](#) > Study Record Detail

Text Size ▾

A Study to Examine the Absorption of GSK561679 in Healthy Male Volunteers**This study has been completed.****Sponsor:**

GlaxoSmithKline

Information provided by:

GlaxoSmithKline

ClinicalTrials.gov Identifier:

NCT00539136

First received: October 3, 2007

Last updated: October 14, 2010

Last verified: October 2010

[History of Changes](#)[Full Text View](#)[Tabular View](#)[Study Results](#)[Disclaimer](#)[How to Read a Study Record](#)**Purpose**

This study will be conducted in healthy volunteers to investigate the absorption of GSK561679 using Gamma Scintigraphy, PillCam™ SB capsule and the acoustic vest.

Condition	Intervention	Phase
Healthy Subjects	Drug: GSK561679 tablet or solution	Phase 1

Study Type: **Interventional**Study Design: **Allocation: Non-Randomized****Endpoint Classification: Pharmacokinetics Study****Intervention Model: Crossover Assignment****Masking: Open Label****Primary Purpose: Diagnostic**

Official Title: An Open-label, Single-dose, Non-randomized, Balanced Design Three-way Cross-over Study to Examine the Variability in Absorption of GSK561679 Using Gamma Scintigraphy, PillCam™ SB Capsule and the Acoustic Vest in Healthy Males Volunteers

Resource links provided by NLM:[MedlinePlus](#) related topics: [Nuclear Scans](#)[U.S. FDA Resources](#)**Further study details as provided by GlaxoSmithKline:****Primary Outcome Measures:**

- Pharmacokinetic scope of GSK561679 after application in a solution and in a new tablet formula per treatment phase Complete gastric emptying of radioactive marker after application of GSK561679 Complete tablet breakdown per treatment phase

Secondary Outcome Measures:

- AUC(0-24h), AUC(0-t), AUC(0-∞) of GSK561679 after administration of GSK561679 in a solution (fasted) and in a new "optimized" tablet formulation (fasted and fed).
- λ_{Z} (and $t_{1/2}$), t_{lag} , K_a , the time to absorb the 25, 50 and 90% of the total absorbed dose
- Other pharmacokinetic parameters of GSK561679 per treatment phase •Safety and tolerability parameters, including adverse events, clinical laboratory,vital signs and 12-lead ECGs measured at each dosing period and throughout the study

Enrollment: 12

Study Start Date: October 2007

Study Completion Date: March 2008

Primary Completion Date: March 2008 (Final data collection date for primary outcome measure)

Intervention Details:

Drug: GSK561679 tablet or solution

Other Name: GSK561679 tablet or solution

Eligibility

Ages Eligible for Study: 18 Years to 55 Years

Genders Eligible for Study: Male

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Healthy males aged 18-55 years, inclusive.
- Healthy subjects, defined as individuals who are free from clinically significant illness or disease (including peptic ulcer disease and psychiatric illness) as determined by their medical and psychiatric history (including family), physical examination, laboratory studies, and other tests.
- Body weight $\geq$ 50 kg (110 lbs) and BMI within the range 18.5-29.9 kg/m² inclusive
- Demonstrates no evidence of active disease, physical or mental impairment.
- Self-administered Beck Depression Inventory II scale total score no greater than 9, and suicide question score of zero.
- Non-smoker (abstinence from smoking for at least 6 months before the start of the study).
- Normal electrocardiogram (subjects must have no clinically significant abnormalities on a 12-lead ECG).
- Agree to remain in the clinic for the time defined in the protocol.
- Signed and dated written informed consent prior to admission to the study.
- The subject is able to understand and comply with protocol requirements, instructions and protocol-stated restrictions.

Exclusion Criteria:

- As a result of any of the medical interview, physical examination, evaluation of mental state and psychiatric history or screening investigations, the physician responsible considers the subject unfit for the study.
- History of clinically significant psychiatric illness.
- Any history of suicidal attempts or behavior.
- Any history of an endocrine disorder including, but not limited to, diabetes or disorders of the hypothalamus, pituitary, adrenal, or thyroid glands, or gonadal disorder or dysfunction of the reproductive organs.
- History of long QT syndrome (personal or family) or other cardiac conduction disorder, or other clinically significant cardiac disease.
- Current or recent (within one year) gastrointestinal disease; a history of malabsorption, esophageal reflux, irritable bowel syndrome or intestinal obstruction; frequent (more than once a week) occurrence of heartburn; or any surgical intervention (e.g., cholecystectomy) which would be expected to influence the absorption of drugs.
- History or presence of allergy to the study drug or drugs of this class, or a history of drug or other allergy that, in the opinion of the physician responsible, contraindicates their participation.
- LFTs elevated >1.5 times above the reference range at pre-study screening that remain elevated with a repeat LFT (to be discussed with the sponsor, if necessary).
- Any other clinically significant laboratory abnormality.
- The subject has a screening ECG with values outside ranges specified in protocol.
- A semi-supine systolic blood pressure less than 90 mmHg or greater than 140 mmHg or a semi-supine diastolic blood pressure of less than 60 mmHg or greater than 90mmHg; or a radial pulse rate less than 40 bpm or more than 90 bpm.
- A positive pre-study HIV 1, Hepatitis B surface antigen or positive Hepatitis C antibody result within 3 months of the start of the study. Subjects with a negative Hepatitis B, C and HIV test in last 3 months will not be required to repeat the tests.
- The subject has a positive pre-study urine drug/alcohol screen.
- History of regular alcohol consumption averaging 21 drinks/week within 6 months of screening.
- Average daily caffeine intake equivalent to > 4 cups of coffee or > 6 cups of tea.
- Consumption of grapefruit juice or grapefruit within 14 days prior to the first dose of study medication.
- The subject is a vegetarian and/or has specific dietary requirements which would prevent them from eating the meals provided during the study.
- Use of prescription or non-prescription drugs, including vitamins, herbal and dietary supplements (including St John's Wort) within 7 days (or 14 days if the drug is a potential enzyme inducer) or 5 half-lives (whichever is longer) prior to the first dose of study medication, unless in the opinion of the Investigator and sponsor the medication will not interfere with the study procedures or compromise subject safety.
- An unwillingness to use a condom/spermicide during sexual intercourse with pregnant or lactating women from the time of the first dose of study medication until five half lives following administration of the last dose of study medication.
- An unwillingness to use a condom/spermicide in addition to having their female partner use another form of contraception such as an IUD, diaphragm with spermicide, oral contraceptives, injectable progesterone, subdermal implants or a tubal ligation if the woman could become pregnant from the time of the first dose of study medication until 84 days following administration of the last dose of study medication.
- The subject has received an investigational drug or participated in any other research trial within 30 days or 5 half-lives, or twice the duration of the biological effect of any drug (whichever is longer) prior to the first dose of current study medication.
- Where participation in the study would result in donation of excess of 600 mL blood within a 56 day period.
- Radiation exposure, including that from the present study, exceeding a cumulative total effective dose equivalent of 10mSv over the last 3 years. Radiation exposure from previous clinical trials will be included, but clinical (therapeutic or diagnostic) radiation exposures will not be included.
- Radiation exposure from clinical trials, including that from present study, and from diagnostic X-rays, but excluding background radiation, exceeding a target organ (colon) dose of 50mSv (5 rems) from a single dose within the last 30 days or a cumulative dose of 150mSv (15 rems) in the last twelve (12) months. No subject whose occupation requires monitoring for radiation exposure will be enrolled in the study.

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00539136

Locations

United States, Kentucky

GSK Investigational Site
Lexington, Kentucky, United States, 40503

Sponsors and Collaborators

GlaxoSmithKline

Investigators

Study Director: GSK Clinical Trials, MD GlaxoSmithKline

► More Information

No publications provided

Responsible Party: Study Director, GSK
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