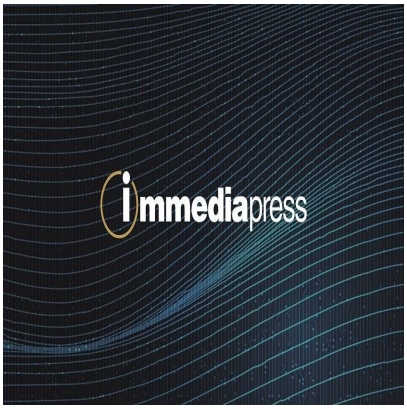

RedHill Biopharma Advancing Opaganib Options For Ebola Virus Disease Outbreak

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Amid the rapidly evolving Ebola virus disease (EVD) outbreak involving the rare Bundibugyo ebolavirus sub-type, for which there are no approved medications or vaccines, RedHill Biopharma is actively discussing potential collaborations for clinical advancement of opaganib1, including the World Health Organizationâ??s (WHO) SOLIDARITY CORE clinical trial platform

Opaganib EVD rationale (analogous to EVD treatment pathway):

Opaganib, an investigational SPHK2 inhibitor drug, offers a novel potential approach to strengthen global infectious disease preparedness and biodefense:

The Company has provided available supply readiness, safety and efficacy data to aid rapid discussions to enable clinical exploration of the potential synergies of opaganib host-directed therapy in addressing a growing global public health threat

TEL AVIV, Israel and RALEIGH, N.C., June 3, 2026 /PRNewswire/ â?? RedHill Biopharma Ltd. (Nasdaq: RDHL) (â??RedHillâ?• or the â??Companyâ?•), a specialty biopharmaceutical company, today announced that it is actively discussing potential collaborations for advancement of its investigational oral drug, opaganib, to combat EVD, which can be fatal in approximately half of all cases7, including the World Health Organizationâ??s (WHO) SOLIDARITY CORE clinical trial platform and pharma collaborations.

Gilead Raday, Chief Operating Officer and Head of R&D at RedHill said: â??Opaganib sits in a distinct category as a host-directed agent which can be added to direct-acting antivirals, representing an opportunity to enhance global infectious disease preparedness and biodefense infrastructure against

EVD, while also being preferentially suited to the logistical challenges found on the ground during these tragic outbreaks.â?•

Peer-reviewed published data shows opaganibâ??s host-direction action stems from its ability to simultaneously inhibit three sphingolipid-metabolizing enzymes in human cells (SPHK2, DES1 and GCS), altering the cellular lipid balance and enabling inhibition of replication of viruses like SARS-CoV-2 and Ebola. In EVD specifically, opaganib offers a potential dual mechanism of action; blocking the PI3K/Akt pathway critical for filovirus entry and suppressing NLRP3 inflammasome and reducing IL-6/TNFÎ± and S1P-mediated vascular permeability (addressing immune dysregulation and vascular leak).

Proactively, and upon request, the Company has provided information to relevant government, industry and other organizations, regarding supply readiness and all available clinical and preclinical safety and efficacy data to aid rapid clinical and regulatory discussions.

Opaganib has demonstrated its safety and tolerability profile in more than 470 participants in multiple clinical studies and expanded access use, including a large global Phase 2/3 study in hospitalized patients with moderate to severe COVID-19, published in Microorganisms
2. Opaganib is an investigational new drug. It has not been approved by any regulatory authority and is not available for commercial distribution. Inclusion in the WHO CORE platform cannot be guaranteed.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on U.S. development and commercialization of drugs for gastrointestinal diseases, infectious diseases and oncology.

Visit www.redhillbio.com / X.com/RedHillBio for more information about the Company

Forward-Looking Statements

This press release contains â??forward-looking statementsâ?• within the meaning of the Private Securities Litigation Reform Act of 1995 and may discuss investment opportunities, stock analysis, financial performance, investor relations, and market trends. Such statements may be preceded by the words â??intends,â?• â??may,â?• â??will,â?• â??plans,â?• â??expects,â?• â??anticipates,â?• â??projects,â?• â??predicts,â?• â??estimates,â?• â??aims,â?• â??believes,â?• â??hopes,â?• â??potentialâ?• or similar words, and include, among others, statements regarding the potential for opaganib to be accepted into Ebola virus disease control programs or, if accepted, the ability to demonstrate its efficacy. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Companyâ??s control and cannot be predicted or quantified, and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation: the risk that opaganib is not accepted into Ebola virus disease control programs, or if accepted, that it does not demonstrate efficacy; the risk that development of RHB-204 for Crohnâ??s disease may not be completed, or if completed may not be approved or may not achieve commercial success; the risk that opaganib is not effective against the indications for which we develop our products; the risk that RHB-102 (Bekinda) does not effectively reduce GLP-1/GIP-related nausea, vomiting and diarrhea; the risk regarding the Companyâ??s ability to regain and maintain compliance

with Nasdaqâ??s listing requirements, including the minimum bid price requirement; the risk that the addition of new revenue generating products or out-licensing transactions will not occur; the risk that the Company will not receive future milestone payments under its existing agreements or that they will be less than anticipated; the risk of current uncertainty regarding U.S. government research and development funding and that the U.S. government is under no obligation to continue to support development of our products and can cease such support at any time; the risk that acceptance onto the RNCP Product Development Pipeline or other governmental and non-governmental development programs will not guarantee ongoing development or that any such development will not be completed or successful; the risk that the FDA does not agree with the Companyâ??s proposed development plans for its programs; the risk that the Companyâ??s development programs and studies may not be successful and, even if successful, such studies and results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional studies may be required; the risk that the Company will not successfully commercialize its products; as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Companyâ??s research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Companyâ??s ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of any necessary commercial companion diagnostics; (iii) the extent and number and type of additional studies that the Company may be required to conduct and the Companyâ??s receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Companyâ??s therapeutic candidates and Talicia; (v) the Companyâ??s ability to successfully commercialize and promote Talicia; (vi) the Companyâ??s ability to establish and maintain corporate collaborations; (vii) the Companyâ??s ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Companyâ??s therapeutic candidates and the results obtained with its therapeutic candidates in research, pre-clinical studies or clinical trials; (ix) the implementation of the Companyâ??s business model, strategic plans for its business and therapeutic candidates; (x) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) the Companyâ??s ability to collect on its judgement against Kukbo; (xiii) estimates of the Companyâ??s expenses, future revenues, capital requirements and needs for additional financing; (xiv) the effect of patients suffering adverse experiences using investigative drugs under the Companyâ??s Expanded Access Program; (xv) competition from other companies and technologies within the Companyâ??s industry; and (xvi) the hiring and employment commencement date of executive managers. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Companyâ??s filings with the Securities and Exchange Commission (SEC), including the Companyâ??s Annual Report on Form 20-F filed with the SEC on April 27, 2026. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise unless required by law.

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Category: R&D

1 Opaganib is an investigational new drug, not available for commercial distribution.

2 Neuenschwander FC, Barnett-Griness O, Piconi S, Maor Y, Sprinz E, Assy N, Khmelnitskiy O, Lomakin NV, Goloshchekin BM, Nahorecka E, et al. Effect of Opaganib on Supplemental Oxygen and Mortality in Patients with Severe SARS-CoV-2 Based upon FIO2 Requirements. Microorganisms. 2024; 12(9):1767. https://doi.org/10.3390/microorganisms12091767

3 Antiviral Activity of Opaganib, a First-in-class Sphingolipid Modulator. Rekha G. Panchal1*, Raina Kumar1, Eric Nguyen1#, LTC Jeffrey Kugelman1, Janet Skerry1, Xiaoli Chi1, Ashley Mcaleese1#, Aura R. Garrison, Mark Levitt, Gilead Raday, Patricia Anderson, Sara Johnston, Reza Fathi, LTC Robert Haupt United States Army Medical Research Institute of Infectious Diseases

4 Repeat study showed 20% vehicle survival vs. 10% opaganib; mixed results across the two animal models (including the vehicle only group inter study variability) underscore model variability.

5 Sphingosine Kinases Promote Ebola Virus Infection and Can Be Targeted to Inhibit Filoviruses, Coronaviruses, and Arenaviruses Using Late Endocytic Trafficking to Enter Cells. Corina M. Stewart, Yuxia Bo, Kathy Fu, Mable Chan, Robert Kozak, Kim Yang-Ping Apperley, GeneviÃ¨ve Laroche, Redaet Daniel, AndrÃ© M. Beauchemin, Gary Kobinger, Darwyn Kobasa, and Marceline CÃ´tÃ©. ACS Infectious Diseases 2023 9 (5), 1064-1077. DOI: 10.1021/acsinfecdis.2c00416

6 Sphingosine Kinases Promote Ebola Virus Infection and Can Be Targeted to Inhibit Filoviruses, Coronaviruses, and Arenaviruses Using Late Endocytic Trafficking to Enter Cells. Corina M. Stewart, Yuxia Bo, Kathy Fu, Mable Chan, Robert Kozak, Kim Yang-Ping Apperley, GeneviÃ¨ve Laroche, Redaet Daniel, AndrÃ© M. Beauchemin, Gary Kobinger, Darwyn Kobasa, and Marceline CÃ´tÃ©. ACS Infectious Diseases 2023 9 (5), 1064-1077. DOI: 10.1021/acsinfecdis.2c00416

7 https://www.who.int/health-topics/ebola#tab=tab_1

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View original content:https://www.prnewswire.co.uk/news-releases/redhill-biopharma-advancing-opaganib-options-for-ebola-virus-disease-outbreak-302790437.html

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Categoria

1. Comunicati

Tag

1. ImmediaPress

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