NEWS RELEASE

Ebola Cases and Deaths Rapidly Mount - RedHill Updates on Opaganib Emergency Outbreak Development

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Professor Pauline Byakika-Kibwika, Vice Chancellor, MUST: "There is an urgent need for additional therapeutic options, and with an oral formulation, ease of administration, human safety database and supportive data, host-directed antiviral opaganib warrants immediate evaluation as a potential treatment candidate for Bundibugyo ebolavirus (BDBV)"

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Development of opaganib for Ebola is supported by preclinical and clinical safety and efficacy data from multiple studies, including in combination with direct acting antiviral Veklury® (remdesivir, Gilead Sciences)

TEL AVIV, Israel and RALEIGH, N.C., July 28, 2026 /PRNewswire/ -- RedHill Biopharma Ltd. (NASDAQ: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today provided an update on the development of opaganib[1] for Ebola virus disease (EVD) as the number of confirmed Bundibugyo ebolavirus (BDBV) cases and deaths has increased substantially to 3221 cases and 1407 deaths[2].

Finalization of development next steps and potential partnership discussions are ongoing, including with the Emergency Task Force expert group of the African Medicines Agency (equivalent to EMA/FDA and designed to coordinate and harmonize drug approvals across Africa), the Ugandan Ministry of Health and Mbarara University of Science and Technology (MUST), alongside liaison with the Scientific Advisory Committee of the Democratic Republic of Congo (DRC).

"The current Bundibugyo ebolavirus (BDBV) outbreak continues to pose a significant public health challenge, despite the extraordinary efforts of healthcare workers and public health authorities," **said Professor Pauline Byakika-Kibwika, Vice Chancellor, Mbarara University of Science and Technology (MUST)**. "The absence of proven therapies for Bundibugyo ebolavirus disease underscores the urgent need to evaluate promising treatment options. Opaganib is a host-directed antiviral with an oral formulation, an established human safety profile, and encouraging preclinical and clinical evidence. Evaluating this candidate during the current outbreak could broaden the therapeutic options available and potentially help improve outcomes for patients affected by Bundibugyo ebolavirus disease."

"Opaganib's potential role in the ongoing Ebola outbreak as an add-on therapy to remdesivir is supported by both clinical and non-clinical data. Analogous to an EVD treatment pathway, Phase 3 severe COVID-19 clinical data showed antiviral activity when given with remdesivir, reducing mortality by 70.2% and improving median time to viral RNA clearance with no additional safety signals – with safety and tolerability demonstrated in 470 clinical trial participants," **said Gilead Raday, Chief Operating Officer and Head of R&D at RedHill**. "Preclinically, United States Army Medical Research Institute of Infectious Diseases (USAMRIID)-funded studies showed opaganib inhibition of EVD in human macrophages, increased survival rates in an opaganib treated group, and a synergistic effect with remdesivir. We will work to ensure that any required supplies of opaganib are rapidly made available to potential partners seeking to fight the deadly effects of Ebola."

Opaganib Ebola virus disease (EVD) rationale:

- **Phase 3 clinical antiviral activity** (severe COVID-19, analogous to EVD setting) showing[3]:
  - 70.2% mortality reduction with opaganib given as add-on to best available standard of care (remdesivir

+ corticosteroids): 6.98% (n=3/43) opaganib + SoC vs. 23.4% (n=11/47) placebo + SoC (nominal p=0.034)) - with no additional safety signals
    - Improved median time to viral RNA clearance by ≥4 days in opaganib-treated patients (median 10 days vs. not reached by Day 14 in placebo, HR 1.34, p=0.043)
    - Demonstrated safety and tolerability profile in 470 clinical trial participants
- **Preclinical EVD activity** (United States Army Medical Research Institute of Infectious Diseases (USAMRIID)-funded studies showed[4]:
    - Opaganib inhibition of EVD in human macrophages
    - Increased survival for opaganib group (one of two animal models[5])
    - Synergistic effect when opaganib combined with Gilead Sciences' remdesivir (Veklury®)
- **Opaganib's potential dual mechanism of action against EVD and filovirus-class activity**[6,7,8]:
    - Published literature explicitly validates sphingosine kinases as targets for filovirus inhibition – opaganib is an SPHK2 inhibitor that:
        - May disrupt host-cell components essential for filovirus entry and replication that are conserved across Filoviridae
        - Inhibits PI3K/Akt pathway (required for filovirus entry and membrane trafficking)
        - Suppresses NLRP3 inflammasome, IL-6/TNFα secretion and S1P-mediated vascular permeability (addressing immune dysregulation and vascular leak in viral hemorrhagic fever)
- **Clinical safety data, oral administration and ease of storage and distribution** supports clinical evaluation and possible stockpiling requirements to strengthen global infectious disease preparedness and biodefense

The data, combined with the U.S. government's Biomedical Advanced Research and Development Authority (BARDA) prior selection of opaganib for joint development & funding as a medical countermeasure (MCM) to treat Ebola virus disease (EBOV), provides additional confidence that opaganib may offer a dual mechanism of action against EVD and filovirus-class activity.

Opaganib is in development for multiple oncology, viral, inflammatory and diabetes and obesity-related indications. Opaganib is an investigational new drug. It has not been approved by any regulatory authority and is not available for commercial distribution.

About Ebola virus disease:

According to the Centers for Disease Control and Prevention (CDC), Ebola disease is a rare and often deadly illness, caused by infection by one of a group of four viruses, known as ebolaviruses. Transmission of the disease is mostly through contact with an infected animal (bat or nonhuman primate) or a sick or dead person infected with an

ebolavirus. The course of the illness typically progresses from "dry" symptoms initially (such as fever, aches and pains, and fatigue) and then progresses to "wet" symptoms (such as diarrhea, vomiting and unexplained hemorrhaging, bleeding or bruising) as the person becomes sicker. Currently only Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn, Regeneron Pharmaceuticals, Inc.), a combination of three monoclonal antibodies and Ebanga™ (ansuvimab-zykl, Ridgeback Biotherapeutics, LP), a single monoclonal antibody, are FDA-approved to treat EVD. Both are intravenously administered, direct acting, monoclonal antibody antivirals that bind to glycoproteins on the Ebola virus's surface to prevent the virus from entering a person's cells. There is an urgent need for host-directed small molecule therapies that may be effective against multiple strains of ebolavirus, less likely to be impacted by viral mutation, and that are easy to store, distribute and administer, especially in areas where healthcare services and infrastructures may be sub-optimal.

About Opaganib (ABC294640)

Opaganib is a proprietary first-in-class investigational, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor drug. Potentially broad-acting, it is in development for multiple oncology, viral, inflammatory, metabolic (diabetes and obesity) and additional indications.

Opaganib's suggested mechanism of action, **published** in the journal Drug Design, Development and Therapy, is host-directed and potentially broad-acting and is expected to maintain its effect against emerging viral variants. Opaganib is thought to work through the inhibition of multiple pathways, the induction of autophagy and apoptosis, and disruption of viral replication, through simultaneous inhibition of three sphingolipid-metabolizing enzymes in human cells (SPHK2, DES1 and GCS).

Opaganib has received Orphan Drug designation from the FDA for the treatment of neuroblastoma and cholangiocarcinoma. A Bayer-supported 60-patient placebo-controlled randomized Phase 2 study is ongoing to evaluate the efficacy of opaganib in combination with Bayer's darolutamide in men with metastatic castrate-resistant prostate cancer (mCRPC), testing the potentially enhancing effect of opaganib in patients with a poor prognosis[9]. Opaganib also has a Phase 1 chemoradiotherapy study protocol ready for FDA-IND submission.

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**.

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. RedHill promotes the FDA-approved gastrointestinal drug **Talicia®,** for the treatment of Helicobacter pylori (H. pylori) infection in adults[10], with a U.S. co-commercialization agreement with Cumberland Pharmaceuticals (acquired by Apotex Health Corp. July 1, 2026). RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anti-inflammatory, antiviral, metabolic and anticancer activity, targeting multiple indications with a track record of U.S. government and academic collaborations intended for medical countermeasure development including for EVD, radiation exposure indications such as GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and an ongoing Phase 2 study in prostate cancer in combination with darolutamide; (ii) **RHB-102 (Bekinda)**, with a planned Phase 2 proof-of-concept study for GLP-1/GIP receptor agonist-associated GI intolerance, positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis, positive results from a U.S. Phase 2 study for IBS-D and potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting. RHB-102 is partnered with Hyloris Pharmaceuticals (EBR: HYL) for worldwide development and commercialization outside North America; (iii) **RHB-204**, a next-generation optimized formulation of RHB-104, with a planned Phase 2 study for Crohn's disease (based on RHB-104's positive Phase 3 Crohn's disease study results); and (iv) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, including COVID-19 and also targeting multiple cancer and inflammatory gastrointestinal diseases.

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Forward-Looking Statements

This press release contains "forward-looking statements" 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 "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" 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 Company'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 Crohn'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 Company's ability to

regain and maintain compliance with Nasdaq'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 Company's proposed development plans for its programs; the risk that the Company'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 Company'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 Company'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 Company'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 Company's therapeutic candidates and Talicia; (v) the Company's ability to successfully commercialize and promote Talicia; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) the Company'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 Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, pre-clinical studies or clinical trials; (ix) the implementation of the Company'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 Company's ability to collect on its judgement against Kukbo; (xiii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiv) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xv) competition from other companies and technologies within the Company'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 Company's filings with the Securities and Exchange Commission (SEC), including the Company'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

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

[2] Numbers reported 28 July 2026: **https://www.cdc.gov/ebola/situation-summary/index.html**

[3] 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**

[4] Antiviral Activity of Opaganib, a First-in-class Sphingolipid Modulator. Rekha G. Pancha, Raina Kumar, Eric Nguyen, LTC Jeffrey Kugelman, Janet Skerry, Xiaoli Chi, Ashley Mcaleese, 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

[5] 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.

[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, Geneviève Laroche, Redaet Daniel, André M. Beauchemin, Gary Kobinger, Darwyn Kobasa, and Marceline Côté. ACS Infectious Diseases 2023 9 (5), 1064-1077. DOI: 10.1021/acsinfecdis.2c00416

[7] Huang F, Xiujuan Shi PZ, Xingbo Song YS, Sun P, Liu B, Therapeutic potential of the sphingosine kinase 2 inhibitor opaganib, Pharmaceutical Science Advances, Volume 4, 2026, 100125, ISSN 2773-2169,

https://doi.org/10.1016/j.pscia.2026.100125.

[8] Smith CD, Maines LW, Keller SN, Katz Ben-Yair V, Fathi R, Plasse TF, Levitt ML. Recent Progress in the Development of Opaganib for the Treatment of Covid-19. Drug Des Devel Ther. 2022 Jul 12;16:2199-2211. doi: 10.2147/DDDT.S367612. PMID: 35855741; PMCID: PMC9288228.

[9] **https://www.redhillbio.com/news/news-details/2025/RedHill-Announces-Initiation-of-Phase-2-Study-of-Opaganib-and-Darolutamide-in-Advanced-Prostate-Cancer/default.aspx**

[10] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of H. pylori infection in adults. For full prescribing information see: **www.Talicia.com**.

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