RedHill's RHB-107 Included in U.S. Government-Supported COVID-19 Platform Trial and Cleared for Initiation by FDA

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RHB-107 (upamostat) accepted for inclusion in ACESO's PROTECT adaptive platform trial for early COVID-19 outpatient treatment to be conducted in the U.S., Thailand, Ivory Coast and South Africa

The substantial 300-patient Phase 2 study, predominantly funded by the U.S. Government Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), has received FDA clearance to start (expected Q3/23) and is estimated to be completed by end of 2024

If approved, RHB-107, a novel, oral, once-daily, broad-acting, host-directed antiviral is expected to act independently of viral spike protein mutations¹, would potentially target a multi-billion-dollar early COVID-19 treatment market

RHB-107 successfully met the primary endpoint of safety and tolerability and delivered promising efficacy results, including marked reduction in hospitalization due to COVID-19 in a U.S. Phase 2 study²

TEL AVIV, Israel and RALEIGH, NC, July 31, 2023 /PRNewswire/ -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that RHB-107 (upamostat)³ has been accepted for inclusion in the Austere environments Consortium for Enhanced Sepsis Outcomes' (ACESO) U.S.
Government-supported PROTECT multinational platform trial for early COVID-19 outpatient treatment to be conducted in the U.S., Thailand, Ivory Coast and South Africa. The Company also announced that the Phase 2 study, predominantly funded by the U.S. Government Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), has received FDA clearance to start and is estimated to be completed by end of 2024.

Expected to begin enrolling patients in Q3 2023, the ACESO PROTECT study is an adaptive, randomized, double blind, multi-site Phase 2 platform trial, being conducted by researchers from ACESO and partner organizations, and administered by the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF). The study will compare investigational products (IPs) to control, in standard-risk, non-hospitalized adult SARS-CoV-2 infected participants with at least two moderate-severe symptoms at baseline. RHB-107 is the initial drug being evaluated in the early treatment arm of the study. The primary efficacy assessment in the early treatment indication will be time to sustained alleviation or resolution of COVID-19 symptoms. Participants will be followed for a period of up to 12 weeks.

Selection of investigational products for inclusion in the study was based on review of the preclinical and early clinical data, evaluating, safety, tolerability, and efficacy of the IP. Selection is also based on route of administration and product availability. Products with oral, subcutaneous, and intramuscular delivery modes have been prioritized due to acceptability and feasibility of administration.

"Having RHB-107 accepted for inclusion in the PROTECT platform study, following an extensive review of the potential value it can bring, by both the scientific and governmental bodies involved in the study offers us a chance to further verify the promising efficacy results, including 100% reduction in hospitalization due to COVID-19, that we delivered in our earlier U.S. Phase 2 study," said Gilead Raday, RedHill's Chief Operating Officer and Head of R&D. "RHB-107 is a novel, broad-acting, host-directed antiviral that is expected to act independently of viral spike protein mutations and, if approved, would add to treatment options such as Paxlovid (a multi-billion-dollar product), in the early COVID-19 treatment paradigm. RHB-107’s development runs alongside RedHill’s other U.S. Government-funded program with opaganib, a novel oral drug being developed in collaboration with the National Institutes of Health Radiation and Nuclear Countermeasures Program for Acute Radiation Syndrome."

Data from RHB-107’s U.S. Phase 2 study showed a 100% reduction in hospitalization due to COVID-19, with zero patients (0/41) on the RHB-107 arms versus 15% (3/20) hospitalized for COVID-19 on the placebo-controlled arm (nominal p-value=0.0317). The study also showed an approx. 88% reduction in reported new severe COVID-19
symptoms after treatment initiation, with only 2.4% of the RHB-107 treated group (1/41) versus 20% (4/20) of patients in the placebo-controlled arm (nominal p-value=0.036) reporting new severe COVID-19 symptoms. Further post-hoc analysis showed faster recovery from severe COVID-19 symptoms with a median of 3 days to recovery with upamostat compared to 8 days with placebo.

Discussions for external non-dilutive funding for RHB-107 Phase 3 COVID-19 development, in addition to the platform study, are advancing. Several collaborative projects for pandemic preparedness testing RHB-107, with government and non-government bodies, in a range of preclinical studies against other viral targets are ongoing and under discussion with government and non-government bodies.

About RHB-107 (upamostat)

RHB-107 is a proprietary, first-in-class, once-daily orally administered investigational antiviral, that targets human serine proteases involved in preparing the spike protein for viral entry into target cells. Because it is host-cell targeted, RHB-107 is expected to also be effective against emerging viral variants with mutations in the spike protein.

In addition, RHB-107 inhibits several proteases targeting cancer and inflammatory gastrointestinal disease. RHB-107 has undergone several Phase 1 studies and two Phase 2 studies, demonstrating its clinical safety profile in approximately 200 patients.

RedHill acquired the exclusive worldwide rights to RHB-107, excluding China, Hong Kong, Taiwan and Macao, from Germany’s Heidelberg Pharmaceuticals (FSE: HPHA) (formerly WILEX AG) for all indications.

About HJF

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF), now celebrating its 40th anniversary, is a global nonprofit organization with the mission to advance military medicine. HJF’s scientific, administrative and program operations services empower investigators, clinicians, and medical researchers around the world to make discoveries in all areas of medicine. HJF serves as a trusted and responsive link between the military medical community, federal and private partners, and the millions of warfighters, veterans, and civilians who benefit from military medicine. For more information, visit www.hjf.org.

About the JPEO-CBRND

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) protects the Joint Force by providing medical countermeasures and defense equipment against chemical, biological,
radiological and nuclear (CBRN) threats. JPEO-CBRND’s goal is to enable the Joint Force to fight and win unencumbered by a CBRN environment. JPEO-CBRND facilitates the rapid response, advanced development, manufacturing and acquisition of medical solutions, such as vaccines, therapeutics, and diagnostics, to combat CBRN and emerging threats such as COVID-19. To learn more about JPEO-CBRND’s COVID-19 response, visit https://www.jpeocbrnd.osd.mil/coronavirus exit disclaimer icon or follow JPEO-CBRND on social media at @JPEOCBRND.

About ACESO

The Austere environments Consortium for Enhanced Sepsis Outcomes (ACESO) aims to improve survival for patients with sepsis in resource-limited settings through development of host-based technology solutions and evidence-based clinical management strategies. Founded in 2010, ACESO brings together a consortium comprised of academic, non-profit, governmental, and industry partners that is administered by HJF. ACESO has established a global clinical research network to develop and deliver cutting-edge tools and strategies to save lives in austere settings.

For more information, visit www.aceso-sepsis.org.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs Talicia® for the treatment of Helicobacter pylori (H. pylori) infection in adults⁴, and Aemcolo® for the treatment of travelers’ diarrhea in adults⁵. RedHill’s key clinical late-stage development programs include: (i) opaganib (ABC294640), a first-in-class oral broad-acting, host-directed SPHK2 selective inhibitor with potential for pandemic preparedness, targeting multiple indications with a U.S. Government collaboration for development for Acute Radiation Syndrome (ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 program in oncology; (ii) RHB-107 (upamostat), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness is in late-stage development as a treatment for non-hospitalized symptomatic COVID-19, and is also targeting multiple other cancer and inflammatory gastrointestinal diseases; (iii) RHB-102, with potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting, positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) RHB-104, with positive results from a first Phase 3 study for Crohn's disease; and (v) RHB-204, a Phase 3-stage program for pulmonary nontuberculous mycobacteria (NTM) disease. More information about the Company is available at www.redhillbio.com / https://twitter.com/RedHillBio.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation
Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. 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 the growth in prescriptions will not continue and the addition of new generating products will not occur, that we will not be successful in obtaining non-dilutive development funding for RHB-107, that we will not be successful in increasing sales of our commercial products, including due to market conditions, that the Phase 2/3 COVID-19 study for RHB-107 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 COVID-19 studies for opaganib and RHB-107 are likely to be required, as well as risks and uncertainties associated with 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; (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® and Aemcolo®; (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) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other companies and technologies within the Company's industry. 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 March 17, 2022. 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.

The views expressed in this press release reflect the results of research conducted by the author and do not necessarily reflect the official policy or position of the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., the Department of the Navy, Department of the Army, Department of Defense, nor the United States Government. This project was supported by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND). The study protocol is in compliance with all applicable federal regulations governing the protection of human subjects.

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Category: R&D

[1] Preliminary data from a recent in vitro study


[3] RHB-107 (upamostat) is an investigational new drug, not available for commercial distribution in the United States.


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