



NEWS RELEASE

RedHill Provides R&D Update

5/22/2023

RedHill has elected to terminate RHB-204's U.S. Phase 3 study for Non-tuberculosis Mycobacteria (NTM) disease due to low accrual rate and plans to shift resources to more rapidly advance RHB-107 late-stage development for outpatient treatment of COVID-19

RedHill's advanced pipeline also includes: Opaganib – in collaboration with the U.S. Government's Radiation and Nuclear Countermeasures Program for development as a potential treatment for Acute Radiation Syndrome (ARS) and other indications, RHB-102 – with a potential UK marketing approval submission for oncology support , and additional clinical stage programs

TEL AVIV, Israel and RALEIGH, NC, May 22, 2023 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the termination of RHB-204's^[1] U.S. Phase 3 study for Non-tuberculosis Mycobacteria (NTM) disease due to a very low accrual rate, and the shifting of the Company's resources to advance once-daily, oral RHB-107's^[2] late-stage development for outpatient treatment of COVID-19. This decision is intended to enable the Company to better focus its resources on key pipeline catalysts and revenue-generating product acquisition, while searching for out-licensing partners for RHB-204.

"RHB-204 is an innovative potential treatment for a difficult to treat disease with strong unmet medical need and no current stand-alone first-line therapies. We are hugely grateful to the RHB-204 development team, including the Clinical Research Organizations and trial sites, who have designed and implemented a very smart Phase 3 clinical trial, in addition to securing Qualified Infectious Disease Product and orphan drug designations in both the U.S. and

EU, along with solid intellectual property coverage for RHB-204," said **Gilead Raday, RedHill's Chief Operating Officer, and Head of R&D**. "However, due to the very slow enrolment in NTM and given the current state of the financial markets and the negative biotech sector sentiment, we must focus our limited resources where we believe most value can be generated for our shareholders in the short to medium term and, as such, we are prioritizing RHB-107 for non-hospitalized COVID-19 patients and opaganib for Acute Radiation Syndrome."

About RHB-204

RHB-204 is a Phase 3-stage proprietary, fixed-dose oral capsule containing a combination of clarithromycin, rifabutin and clofazimine, developed for the treatment of pulmonary NTM disease caused by MAC. RHB-204 was granted FDA Fast Track and Orphan Drug Designation, in addition to QIDP Designation under the Generating Antibiotic Incentives Now Act (GAIN Act), extending U.S. post-approval U.S. market exclusivity to a potential total of 12 years. RHB-204 has additionally been granted EU Orphan Designation, providing eligibility for 10 years EU post-approval market exclusivity. RedHill is seeking protection of RHB-204, and its use in treating pulmonary MAC disease, on a global scale, providing protection until 2041.

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 adults^[3], and **Aemcolo**[®] for the treatment of travelers' diarrhea in adults^[4]. RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class oral broad-acting, host-directed SK2 selective inhibitor with potential for pandemic preparedness and targeting multiple indications, including 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 and is in a Phase 3-stage study as treatment for non-hospitalized symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iii) **RHB-102**, with expected 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**, Phase 3-stage for pulmonary nontuberculous mycobacteria (NTM) disease. More information about the Company is available at www.redhillbio.com/ 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 Company will not re-open and/or complete the U.S. Phase 3 clinical study evaluating RHB-204 and that if re-initiated will not be successful or, if successful, will not suffice for regulatory marketing approval without the need for additional clinical and/or other studies; 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 April 28, 2023. 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.

Company contact:

Adi Frish
Chief Corporate & Business Development Officer RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

Category: R&D

[¹] RHB-204 is an investigational new drug, not available for commercial distribution.

[²] RHB-107 is an investigational new drug, not available for commercial distribution.

[³] 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.

[⁴] Aemcolo® (rifamycin) is indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults. For full prescribing information see: www.aemcolo.com.

Logo - https://mma.prnewswire.com/media/1334141/RedHill_Biopharma_Logo.jpg

View original content: <https://www.prnewswire.com/news-releases/redhill-provides-rd-update-301830635.html>

SOURCE RedHill Biopharma Ltd