Press Release

RedHill Biopharma Announces Agreement with NIAID to Evaluate RHB-107 Against COVID-19

RedHill is pursuing both RHB-107 and opaganib as potential treatments for COVID-19

TEL-AVIV, Israel and RALEIGH, N.C., April 20, 2020, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that it has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to provide its investigational drug, RHB-107 (upamostat, WX-671)[1], for testing in non-clinical studies for activity against SARS-CoV-2, the virus that causes coronavirus disease (COVID-19).

RHB-107, an investigational new chemical entity, has been studied in more than 300 people across 10 clinical studies, including two completed Phase 2 studies in oncology patients and several Phase 1 studies in healthy volunteers and oncology patients. These studies helped establish the safety and tolerability of RHB-107 in humans. RHB-107 is a serine protease inhibitor active against a number of human trypsins and several other related serine proteases. Inhibition of serine proteases, including trypsins, may inhibit viral attachment and replication and decrease lung damage from viral pneumonia[2].

RHB-107 was selected by NIAID for in vitro testing, following evaluation by NIAID of data on the drug's possible mechanism of action and potential activity against SARS-CoV-2.

[1] RHB-107 (upamostat, WX-671) is an investigational new drug, not available for commercial distribution.

[2] Tsujimura S, et al. Bolus infusion of human urinary trypsin inhibitor improves intractable interstitial pneumonia in patients with connective tissue diseases. Rheumatol 2008;47:907-13; Yamada H, et al. Sendai virus infection up-regulates trypsin I and matrix metalloproteinase-9 triggering viral multiplication and matrix degradation in rat lungs and lung L2 cellls. Arch Virol 2006;151:2529-37.

"RHB-107 is the second investigational drug that RedHill is evaluating for COVID-19, underscoring our commitment to the global efforts to develop a treatment for patients with this disease," **said Terry F. Plasse MD, Medical Director at RedHill.** "This new agreement will facilitate pre-clinical evaluation of RHB-107 as a potential COVID-19 treatment."

In parallel with the RHB-107 program, RedHill is evaluating another novel investigational drug, opaganib (Yeliva®, ABC294640), as a potential treatment for SARS-CoV-2 infection. A compassionate use program of opaganib is underway in Israel, with several patients treated to date, with preliminary positive outcomes. In order to facilitate access to opaganib, various programs are currently under discussions in other countries and an Investigational New Drug (IND) application was submitted to the U.S. Food and Drug Administration (FDA) to evaluate opaganib in a clinical study in adults diagnosed with COVID-19 and pneumonia.

To find out more about RedHill Biopharma's Expanded Access policy, please visit: www.redhillbio.com/expandedaccess.

About RHB-107 (upamostat)

RHB-107 is a proprietary, first-in-class, orally-administered potent inhibitor of several serine proteases targeting cancer, inflammatory lung diseases and gastrointestinal diseases. RHB-107 has undergone several Phase 1 studies and two Phase 2 proof-of-concept studies demonstrating its clinical safety profile in over 300 patients. RedHill acquired the exclusive worldwide rights to RHB-107, excluding China, Hong Kong, Taiwan and Macao, from Germany's Heidelberg Pharmaceuticals (formerly WILEX AG) for all indications.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal diseases. RedHill promotes the gastrointestinal drugs **Movantik®** for opioid-induced constipation in adults[3], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[4] and **Aemcolo®** for the treatment of travelers' diarrhea in adults[5]. RedHill's key clinical late-stage development programs include: (i) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102** (**Bekinda®**), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **Opaganib (Yeliva®)**, a first-in-class SK2 selective inhibitor, targeting multiple

[3] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.

[4] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin, and rifabutin) is available at: www.Talicia.com.

[5] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.

oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 1/2a study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation, and (vi) **RHB-107 (upamostat)**, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at www.redhillbio.com.

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, including forward-looking statements. 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 pre-clinical or clinical trials of RHB-107 for the treatment of COV-19, if conducted, will not show any improvement in patients, the development risks of early-stage discovery efforts for a disease that is still little understood, including difficulty in assessing the efficacy of opaganib or RHB-107 for the treatment of COVID-19, if at all; intense competition from other companies developing potential treatments and vaccines for COVID-19; the risk that compassionate use programs of opaganib will not show positive outcomes and the effect of a potential occurrence of patients suffering serious adverse events using opaganib under the compassionate use programs 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 a commercial companion diagnostic for the detection of MAP; (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® and Movantik®; (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; (xiv) competition from other companies and technologies within the Company's industry; and (xv) 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 March 4, 2020. 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
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):
Timothy McCarthy, CFA, MBA
Managing Director, Relationship Manager
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com