Press Release

RedHill Biopharma Announces Publication Demonstrating Potential Efficacy of RHB-104 for Crohn's Disease Associated with MAP Infection

- **The peer-reviewed article, authored by scientists from the University of Central Florida, concludes that the triple combination of the RHB-104 active components provides excellent synergistic activity in the inhibition of mycobacterial growth, potentially leading to a new and effective treatment for Crohn's disease associated with *Mycobacterium avium subspecies paratuberculosis* (MAP) infection**

- **RedHill is conducting a first Phase III clinical study with RHB-104 for Crohn's disease (the MAP US study), with nearly 200 patients recruited out of a total of 270 planned, and interim data and safety monitoring board (DSMB) analysis expected in the second half of 2016**

- **The development of RHB-104, a proprietary and potentially ground-breaking therapy with potent intracellular, anti-mycobacterial and anti-inflammatory properties, is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by MAP infection in susceptible patients**

TEL-AVIV, Israel, June 22, 2016 RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases and cancer, today announced the publication of an article demonstrating the potential efficacy of RHB-104 for Crohn's disease associated with *Mycobacterium avium subspecies paratuberculosis* (MAP) infection.

The article was published in the peer-reviewed journal Gut Pathogens and was authored by scientists from the University of Central Florida[1] (UCF) College of Medicine's Burnett School of Biomedical Sciences[2].

RHB-104 is a proprietary and potentially groundbreaking oral antibiotic combination therapy with potent intracellular, anti-mycobacterial and anti-inflammatory properties, currently undergoing a first Phase III study for Crohn's disease and a Phase IIa study for multiple sclerosis. The development of RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by MAP infection in susceptible patients.

The article[3], entitled *"RHB-104 triple antibiotics combination in culture is bactericidal and should be effective for treatment of Crohn's disease associated with Mycobacterium paratuberculosis"* describes a pre-clinical study intended to determine the efficacy of the RHB-104 active components (the antibiotics clarithromycin, clofazimine and rifabutin) against MAP strains isolated from the blood, tissue and milk of Crohn's disease patients. The researchers determined the minimum inhibitory concentrations of the active components, separately and in dual and triple combinations, against 16 MAP clinical strains and 19 other mycobacteria.

The results of the study demonstrated that the RHB-104 active components, in their individual concentrations or in dual combinations, were not as effective against all microorganisms, compared to the triple combination at minimum inhibitory concentrations level. The authors concluded that lower concentrations of the triple combination of RHB-104 active components provided synergistic anti-MAP growth activity compared to individual or dual combinations of the drugs and, consequently, administration of RHB-104 is considered favorable and should lead to tolerable dosage that is desirable for long-term treatment of Crohn's disease.

Dror Ben-Asher, RedHill's CEO, said: "I would like to thank the scientists at the University of Central Florida in Orlando for this article which supports the continued development of RHB-104 for Crohn's disease. RHB-104 is one of RedHill's flagship gastrointestinal programs and is currently undergoing a Phase III study, named the MAP US study, in the U.S. and additional countries. With nearly 200 patients recruited out of a total of 270 planned, the MAP US Phase III study is advancing well and we expect interim data and safety monitoring board (DSMB) analysis during the second half of 2016. The final results from the Phase IIa proof-of-concept study with RHB-104 in multiple sclerosis are also expected in the second half of 2016, following our previous announcement of encouraging preliminary data in March 2016."

Dr. Reza Fathi, Ph.D., RedHill's Senior VP R&D, added: "We are pleased with the important findings described in this article which provide further validation of the synergistic activity and potential efficacy of RHB-104 in eradicating *Mycobacterium avium subspecies*

[1] The University of Central Florida provides laboratory provides services as a sub-contractor as part of RedHill's MAP US Phase III study with RHB-104.

[2] RedHill announced in September 2011 that it had acquired an exclusive license from the University of Central Florida to a patent-protected diagnostic test for the detection of MAP.

[3] Alcedo KP, Thanigachalam S, Naser SA. *RHB-104 triple antibiotics combination in culture is bactericidal and should be effective for treatment of Crohn's disease associated with Mycobacterium paratuberculosis*, Gut Pathogens, 2016, 8:32.

paratuberculosis, or MAP, - a suspected etiological agent of Crohn's disease and possibly additional autoimmune, inflammatory and mycobacterial diseases. The results from this study suggest that RHB-104, if approved, could become a new and effective therapy for the treatment of Crohn's disease."

RHB-104 is currently undergoing a first Phase III study for Crohn's disease in the U.S., Canada, Israel, Australia and additional countries (the MAP US study). Interim analysis of the ongoing randomized, double-blind, placebo-controlled MAP US study is expected in the second half of 2016, after half of the 270 patients planned to be enrolled in the study will have completed 26 weeks of treatment.

RHB-104 is also being evaluated as a treatment for relapsing-remitting multiple sclerosis (RRMS). The open label Phase IIa, proof-of-concept clinical study is evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for RRMS (the CEASE-MS study). RedHill announced encouraging top-line interim results from this study in March 2016. Final results of the completed 48-week study are expected during the second half of 2016.

The MAP US Phase III study and the CEASE-MS Phase IIa study are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

About RHB-104:
Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study) and a second Phase III study which is being prepared (the MAP EU study), RHB-104 is a proprietary and potentially groundbreaking oral antibiotic combination therapy, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a long-term population pharmacokinetic (pop-PK) study is ongoing as part of the Phase III MAP US study. RHB-104 is covered by several issued and pending patents. RedHill is also conducting the CEASE-MS Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (RRMS), with top-line interim results announced.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases and cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing

Phase III study in the U.S. for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) –** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON® -** a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number 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; (v) the Company's ability to establish and maintain corporate collaborations; (vi) 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; (vii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. 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 February 25, 2016. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

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