Press Release

Date: October 22, 2013

RedHill Biopharma Announces FDA Acceptance of IND Application for RHB-105 (*H. pylori*) Phase III Study - to Commence Shortly

- **The Phase III study is expected to commence in the U.S. by the end of this month**
- **RHB-105 is a new and proprietary combination therapy in an oral capsule for the treatment of *H. pylori* bacterial infection**
- **RedHill recently commenced another Phase III study in the U.S. with RHB-104 for the treatment of Crohn's disease**

RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, proprietary formulations and combinations of existing drugs, announced today that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for the ERADICATE Hp study - a Phase III clinical study with RHB-105 for the treatment of *Helicobacter pylori* (*H. pylori*) bacterial infection. The Company plans to commence the Phase III study in the U.S. by the end of this month, subject to final preparations.

The RHB-105 IND acceptance follows a pre-IND meeting held with the FDA in October 2012 and subsequent communications between the Company and the FDA throughout the past year.

RHB-105 is a new and proprietary combination therapy of two antibiotics and a PPI (proton pump inhibitor), in an oral capsule, designed for the treatment of *H. pylori* bacterial infection - a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma.

Existing standard of care combination therapies for *H. pylori* infection have high failure rates due to growing resistance of *H. pylori* to the antibiotics commonly used in such therapies. RHB-105 is composed of a different combination of antibiotics, specifically selected due to their demonstrated superior resistance profile, and offers a new and potentially improved therapeutic alternative with increased efficacy in eradicating *H. pylori* infection.

A Phase II study conducted in Australia with the RHB-105 active agents demonstrated an eradication rate greater than 90% in patients who had previously failed at least one course of standard of care therapy for *H. pylori* infection.

In addition to a potential increase in efficacy, RHB-105's new and proprietary all-in-one oral capsule formulation offers a convenient treatment regimen, potentially improving overall patient compliance and response.

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, and one of ten Americans will suffer from peptic ulcer disease during their lifetime[1]. The sales of *H. pylori* eradication therapies in the U.S. are estimated at approximately $1-1.5 billion annually[2].

Dr. Reza Fathi, RedHill's Senior VP R&D, commented: "The acceptance of the RHB-105 IND application is another major regulatory milestone for RedHill and an important validation of our clinical development program. Current standard therapies for *H. pylori* eradication have high failure rates due to growing resistance. Based on the results from a prior Phase II study, we believe that RHB-105 has the potential to become a preferred treatment for *H. pylori* infection. We are now focused on completing final preparations for the Phase III ERADICATE Hp study with RHB-105, which we expect to commence in the U.S. by the end of this month."

RHB-105 is one of RedHill's leading gastrointestinal (GI) late clinical-stage development programs. The Company announced earlier this month the initiation of the MAP US study - a Phase III clinical study designed to evaluate the safety and efficacy of fixed-dose RHB-104 for the treatment of Crohn's disease. RHB-104 is a proprietary and potentially groundbreaking combination antibiotic therapy in an oral capsule. The randomized, double-blind, placebo-controlled Phase III MAP US clinical study is expected to enroll 240 subjects with moderately to severely active Crohn's disease in approximately 50 clinical sites in the U.S., Canada and Israel.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-

[1] Center of Disease Control and Prevention (CDC) - http://www.cdc.gov/ulcer/

[2] Approximately three million *H. pylori* infected patients are treated per annum in the U.S. (Colin W. Howden, MD, et. Al (2007), The American Journal of Managed Care). Market size is estimated by the Company based on the above and the price of current treatments.

stage, proprietary formulations and combinations of existing drugs. The Company's current product pipeline includes: (i) **RHB-101** - a once-daily formulation of a leading congestive heart failure and high blood pressure drug, with a planned NDA submission in the U.S. subject to further CMC and PK work, and a planned Marketing Authorization Application (MAA) in Europe subject to further CMC work; (ii) **RHB-102** - a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, planned for U.S. New Drug Application (NDA) submission in the first quarter of 2014; (iii) **RHB-103** - an oral thin film formulation of a leading drug for the treatment of acute migraine, with a U.S. NDA accepted for review by the FDA in June 2013 and a PDUFA date of February 3, 2014; (iv) **RHB-104** - a combination antibiotic therapy for the treatment of (a) Crohn's disease, with a first Phase III trial currently underway, (b) multiple sclerosis (MS), with a Phase IIa proof of concept trial currently underway, (c) rheumatoid arthritis (RA), with plans for a Phase IIa proof of concept trial, and (d) systemic lupus erythematosus; (v) **RHB-105** - a combination therapy for *Helicobacter pylori* infection, planned to commence a phase III trial by the end of October 2013, and (vi) **RHB-106** - an encapsulated formulation for bowel preparation ahead of colonoscopy and other GI procedures. For more information please visit: 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. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status 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 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 and approvals; (iv) the 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 interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company under their respective licensing agreements; (x) estimates of the Company's expenses, future revenues, capital requirements and the Company's needs for additional financing; (xi) competitive companies and technologies within the Company's industry; and (xii) 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 From 20-F filed with the SEC on February 19, 2013, and its Reports on Form 6-K. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. 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 made by us or on our behalf as a result of new information, future events or other factors.

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (US):
Lauren Glaser
Vice President
The Trout Group
+1-646-378-2972
lglaser@troutgroup.com