Press Release

Date: October 30, 2013

RedHill Biopharma Initiates Phase III Study of RHB-105 for *H. pylori* Infection

- **RedHill has initiated the patient screening process in the ERADICATE Hp study - a randomized, double-blind, placebo-controlled Phase III study to evaluate the safety and efficacy of RHB-105 as a first-line therapy for *H. pylori* bacterial infection**

- **Subjects will be treated with RHB-105 for a period of 14 days in up to 10 clinical sites in the U.S. and assessed for the primary endpoint of eradication of *H. pylori* infection 28 to 56 days after completion of treatment, with data expected by the second half of 2014**

- **Approximately two-thirds of the world's population is infected with *H. pylori*, a major cause of chronic gastritis, peptic ulcer disease and gastric cancer; existing therapies have high failure rates due to growing *H. pylori* resistance**

- **RedHill recently commenced a Phase III study in the U.S. with another treatment for a digestive system condition - RHB-104 for 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, today announced that it has initiated the patient screening process in the ERADICATE Hp study - a Phase III clinical study in the U.S. designed to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *Helicobacter pylori* (*H. pylori*) bacterial infection. Initiation of the RHB-105 Phase III clinical study follows the necessary approvals including FDA acceptance of the Company's Investigational New Drug (IND) application and Institutional Review Board (IRB) approval.

RHB-105 is a new and proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI), in an all-in-one 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. The RHB-105 combination was originally developed by Professor Thomas Borody, a leading innovator of therapeutic approaches to gastrointestinal tract diseases. Prof. Borody, a member of RedHill's Advisory Board, also developed the first triple therapy for *H. pylori* associated with peptic ulcer disease.

The randomized, double-blind, placebo-controlled Phase III study is expected to enroll 90 subjects with confirmed *H. pylori* infection and non-investigated dyspepsia in up to ten clinical sites in the U.S. Subjects will be randomized in a 2:1 ratio to receive four capsules three times daily, of either RHB-105 or placebo, for a period of 14 days, and will be assessed for the study's primary endpoint of eradication of *H. pylori* infection 28 to 56 days after completion of treatment.

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.

A supporting pharmacokinetic (PK) study of the RHB-105 formulation has commenced in October 2013. In parallel to conducting these Phase III and PK studies, the Company is in ongoing discussions with the FDA regarding RHB-105's planned indication.

Gilead Raday, RedHill's Senior VP Corporate and Product Development, commented: "We are very excited with the initiation of the ERADICATE Hp Phase III clinical trial with RHB-105 for the treatment of *H. pylori* bacterial infection, which follows the commencement earlier this month of RedHill's MAP US Phase III study with RHB-104 for Crohn's disease. The RHB-105 Phase III study is planned to be relatively short, with data expected by the second half of 2014. We hope the

results will support the potential efficacy of this new and proprietary all-in-one oral capsule formulation."

Ira Kalfus, MD, RedHill's Medical Director, added: "The growing prevalence of *H. pylori* resistance to current antibiotic combination therapies is one of the leading factors for the high rate of treatment failures. The promising results of the Phase II study conducted in Australia, which 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, lead us to believe that RHB-105 has the potential of becoming a first-line therapy for the treatment of *H. pylori* infection and to substantially reduce the current treatment failure rate."

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, and approximately 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].

The ERADICATE Hp study will be registered on www.ClinicalTrials.gov, a web-based service by the U.S. National Institute of Health which provides public access to information on publicly and privately supported clinical studies.

The Company commenced on September 2013 a Phase III study in the U.S. with another proprietary antibiotic combination therapy, RHB-104 for the treatment of Crohn's disease - an inflammatory disease of the gastrointestinal system with significant unmet medical need. RHB-104 is a potentially groundbreaking combination antibiotic therapy in oral pill formulation, with potent intracellular, antimycobacterial and anti-inflammatory properties. A second Phase III study with RHB-104 is planned to commence in Europe by mid-2014.

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-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. 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

[1] Center of Disease Control and Prevention (CDC), Division of Bacterial Diseases (DBD) - 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.

for *Helicobacter pylori* infection with a Phase III trial currently underway, 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 Form 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.

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