Press Release

RedHill Biopharma Announces First Patients Dosed in Phase III Study of RHB-105 for *H. pylori* Infection

- **The first patients have been dosed in the ERADICATE Hp study - a randomized, double-blind, placebo-controlled, Phase III study evaluating RHB-105 as a first-line therapy for *H. pylori* bacterial infection**

- **Seven of the eight clinical sites in the U.S. are actively enrolling patients, with the last site expected to commence enrollment shortly; the Phase III data is expected by the third quarter 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 increasing failure rates due to bacterial resistance**

- **RedHill recently commenced dosing in a Phase III study with a different drug, RHB-104, for Crohn's disease, another inflammatory disease of the gastrointestinal system**

TEL-AVIV, Israel, December 17, 2013 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 the first patients have been dosed in the Phase III ERADICATE Hp clinical study in the U.S.

The Phase III ERADICATE Hp clinical study is designed to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *Helicobacter pylori* (*H. pylori*) bacterial infection, a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated

lymphoid tissue (MALT) lymphoma. Seven of the eight clinical sites in the U.S. have commenced enrollment of patients for the ERADICATE Hp study, and the last site is expected to commence enrollment shortly.

"We are very excited by the dosing of the first patients in the Phase III study with RHB-105 for the treatment of *H. pylori* infection. We believe RHB-105 is a potential solution to the growing bacterial resistance and high failure rates of currently available therapies," **said Dr. Reza Fathi, RedHill's Senior VP R&D. Dr. Fathi continued,** "A previous Phase II study conducted with the RHB-105 combination demonstrated an eradication rate of more than 90% in patients who had previously failed standard of care therapy. This positive data leads us to believe that, if approved, RHB-105 could become the preferred first line therapy for *H. pylori* infection. Considering that per patient treatment is only 14 days, we expect data from the ongoing Phase III study to be available by the third quarter of 2014."

Existing standard of care combination therapies for *H. pylori* infection have increasingly high failure rates due to the 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 potential for improved efficacy and superior resistance profile for eradicating *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 patient compliance and convenience.

The randomized, double-blind, placebo-controlled, Phase III study is expected to enroll 90 non-investigated dyspepsia subjects with confirmed *H. pylori* infection in 8 clinical sites in the U.S. Subjects are 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 are assessed for the study's primary endpoint of eradication of *H. pylori* infection 28 to 56 days after completion of treatment.

The ERADICATE Hp study is 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.

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, and approximately 500,000 Americans suffer from peptic ulcer disease annually, which is caused by *H. pylori* bacterial infections. The market of *H. pylori* eradication therapies in the U.S. is estimated at approximately $1-1.5 billion annually[1].

The Company announced in November 2013 that it had commenced dosing in the MAP US study, a Phase III study with RHB-104 - another proprietary antibiotic therapy. RHB-104 is intended for the treatment of Crohn's disease, which, similar to *H. pylori*, is an inflammatory condition of the gastrointestinal system. Crohn's disease is a condition with significant unmet medical needs.

[1] 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 number and the price of current treatments

RHB-104 is a combination antibiotic therapy in oral capsule formulation, with potent intracellular, antimycobacterial and anti-inflammatory properties. It is a potentially groundbreaking therapy that targets the suspected underlying cause of the disease, based on increasing evidence supporting the hypothesis that Crohn's disease is caused by the *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients.

About RHB-105:
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, who developed the first approved triple therapy treatment for *H. pylori* associated with peptic ulcer disease.

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 pipeline of proprietary products includes: (i) **RHB-103** - an oral thin film formulation of a leading drug for the treatment of acute migraines, with a U.S. NDA accepted for review by the FDA in June 2013 and a PDUFA date of February 3, 2014, (ii) **RHB-102** - a once-daily oral pill 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-104** - a combination antibiotic therapy in oral capsule formulation, with potent intracellular, antimycobacterial and anti-inflammatory properties 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, (iv) **RHB-105** - a combination therapy in oral capsule formulation for *Helicobacter pylori* infection, with a Phase III trial currently underway, (v) **RHB-106** - an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy and other GI procedures, and (vi) **RHB-101** - a once-daily formulation of a leading congestive heart failure and high blood pressure drug. 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, technologies and 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.

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