Press Release

RedHill Biopharma Reports Positive PK Results in Support of Ongoing RHB-105 Phase III *H. pylori* Study

- **The positive results from the pharmacokinetic study support the continuation of the ERADICATE Hp study - a Phase III clinical study currently underway in the U.S., evaluating RHB-105 as a first-line therapy for *H. pylori* bacterial infection**

- **The objectives of the PK study were to evaluate RHB-105's pharmacokinetics and bioavailability properties, and to assess safety**

- **RedHill recently announced that the first patients have been dosed in the ERADICATE Hp Phase III study, with data expected by the third quarter of 2014**

TEL-AVIV, Israel, December 23, 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 stage, proprietary formulations and combinations of existing drugs, today reported positive results from a pharmacokinetic (PK) study with RHB-105, a proprietary combination therapy, oral capsule formulation, for eradication of *Helicobacter pylori* (*H. pylori*) infection, a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma.

The results of the PK study, including the pharmacokinetics, bioavailability and safety of RHB-105, are subject to final quality assurance and an independent study report by the Canadian clinical research organization (CRO) which conducted the study. The final independent report from the CRO is expected in the coming weeks.

The objective of the randomized open-label, 2-arm crossover PK study was to evaluate the pharmacokinetics and bioavailability of the RHB-105 all-in-one oral capsule and compare those to the concomitant administration of the three individual active drugs comprising RHB-105. The secondary objective of the PK study was to assess the safety of the RHB-105 combination formulation in healthy volunteers.

The positive results of the PK study provide support for the continuation of the RHB-105 ERADICATE Hp Phase III study that is currently underway in the U.S.

Gilead Raday, RedHill's Senior VP Corporate and Product Development commented: "We are very pleased with the positive results of this pharmacokinetic study with RHB-105. The results have provided further insight into the pharmacokinetic properties of RHB-105 and demonstrated a high safety profile, all of which support the continuation of the ongoing Phase III study with RHB-105 and the product's potential future commercialization prospects."

RedHill recently announced the dosing of the first patients in the Phase III ERADICATE Hp study, designed to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* bacterial infection. Data from this Phase III study is expected to be available by the third quarter of 2014.

Current 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. By contrast, RHB-105 is a different combination of two antibiotics with a proton pump inhibitor, specifically selected due to their potential for improved efficacy and superior resistance profile in 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.

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].

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 as a next-generation therapy, 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.:

[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.

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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