Press Release

RedHill Biopharma Provides Update on Expansion of Ongoing RHB-105 Phase III Study, Targeting Broadened *H. pylori* Indication Authorized by FDA

- **In order to enhance statistical powering and expedite recruitment, RedHill has increased the number of subjects and clinical sites, respectively, in the ongoing RHB-105 Phase III ERADICATE Hp study, with top-line data currently expected in the first half of 2015**

- **FDA has permitted RedHill to pursue with RHB-105 a significantly broader indication than that of existing *H. pylori* therapies, targeting the first line treatment of *H. pylori* infection regardless of ulcer status**

- ***H. pylori*, a major cause of chronic gastritis, peptic ulcer disease and gastric cancer, has recently been named a "qualifying pathogen" by the FDA under the Generating Antibiotic Incentives Now (GAIN) Act, which may lead to the grant of an additional five years of regulatory exclusivity and fast track priority review by the FDA for RHB-105**

- **Approximately two-thirds of the world's population is infected with *H. pylori* and over three million patients are treated annually in the U.S. to eradicate *H. pylori*, with the potential market for *H. pylori* eradication therapies in the U.S. estimated at approximately $1-1.5 billion annually**

TEL-AVIV, Israel, August 27, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today provided an update on the ongoing RHB-105 Phase III ERADICATE Hp study. In order to enhance statistical powering and expedite recruitment, RedHill is expanding the study to include, respectively, additional subjects and clinical sites. The Company further announced that, based on prior discussions, the U.S. Food and Drug Administration (FDA) has authorized RedHill to pursue a new, distinct and broader indication with RHB-105, a proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI) in an all-in-one oral capsule for the first line treatment of *Helicobacter pylori (H. pylori)* infection. The ongoing Phase III ERADICATE Hp study follows a successful Phase II study in Australia with 130 subjects, as well as a successful PK study conducted in 2013.

As part of an amendment to the ongoing RHB-105 Phase III ERADICATE Hp study protocol, currently being reviewed by FDA, RedHill has increased the number of subjects to be enrolled from 90 to 120. RedHill believes that the increased number of subjects, as well as other amendments to the study protocol, should improve the study's statistical powering and reduce the potential impact of non-compliant subjects in meeting the study's primary endpoint of *H. pylori* eradication. RedHill is also increasing the total number of clinical sites from 8 to 12 in order to expedite recruitment. In light of the changes to the study protocol, top-line data from the study is currently expected in the first half of 2015.

Following prior discussions with the FDA, RedHill has received authorization from the FDA to pursue a new and significantly broader indication with RHB-105. While current standard treatments for *H. pylori* are typically indicated to treat patients with active or recent history of ulcers, RedHill's RHB-105 new intended indication will target *H. pylori* infection as a first line treatment regardless of ulcer status. If approved, RHB-105 may be the first *H. pylori* eradication therapy to pursue this broader indication, which would significantly expand the potential patient population for the drug.

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, and over three million patients are treated annually in the U.S. to eradicate *H. pylori* infection[1]. The potential market of *H. pylori* eradication therapies in the U.S. is estimated at approximately $1-1.5 billion annually[2].

H. pylori has recently been added to the FDA's list of "qualifying pathogens" under the Generating Antibiotic Incentives Now (GAIN) Act. As a result, new drugs indicated to treat *H. pylori* may be designated as a Qualified Infectious Diseases Product (QIDP) and receive an additional five years of exclusivity, along with fast track status and priority review by the FDA.

[1] Javier P. Gisbert MD, PhD, et. al (2013), Helicobacter Pylori "Test-and-Treat" Strategy for Management of Dyspepsia: A Comprehensive Review, *Clinical and Translational Gastroenterology* (2013) 4(3): e32.

[2] Approximately three million *H. pylori* infected patients are treated per annum in the U.S. (Javier P. Gisbert, MD, et. al (2013) Clinical and Translational Gastroenterology). Potential market size is estimated by the Company based on the above number and the estimated prices of current treatments of *H. pylori* infection in the U.S.

Gilead Raday, RedHill's Senior VP Product and Corporate Development, said: "With over half of the initial planned number of patients already recruited, the expansion of the RHB-105 Phase III study is expected to further improve the study's statistical powering. Following the changes made, we expect top-line results during the first half of 2015 and, subject to further discussions with the FDA, plan to conduct a confirmatory Phase III study to support NDA filing. The addition of *H. pylori* to the "qualifying pathogens" list by the FDA could potentially grant RHB-105 a Qualified Infectious Disease Product (QIDP) designation, providing fast track status, priority review and an additional five years of exclusivity post approval."

Ira Kalfus, MD, RedHill's Medical Director, added: "We are excited to pursue a broader indication for the treatment of *H. pylori* infection with RHB-105. Ulcer patients represent only a limited segment of the potential market for *H. pylori* eradication therapies. We hope that RHB-105's broadened indication, along with its potentially improved efficacy and convenient treatment regimen will assist patients suffering from *H. pylori* infection in achieving better care."

The ERADICATE Hp randomized, double-blind, placebo-controlled Phase III study is designed to evaluate the safety and efficacy of RHB-105 for the treatment of *H. pylori* infection in non-investigated dyspepsia subjects with confirmed *H. pylori* infection. Subjects in the study are randomized to receive either RHB-105 or a placebo for a period of 14 days and are assessed for the study's primary endpoint of eradication of *H. pylori* infection 28 to 35 days after completion of treatment.

Current standard of care combination therapies for *H. pylori* infection have increasingly high failure rates due to growing antibiotic resistance of *H. pylori*. RHB-105 is a novel 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.

A Phase II study conducted in Australia with the RHB-105 active agents demonstrated an eradication rate greater than 90% in 130 patients who had previously failed at least one course of standard of care therapy for *H. pylori* infection.

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 with a planned indication for treatment of *H. pylori* infection. *H. pylori* bacterial infection is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. RHB-105 is currently undergoing a first Phase III clinical study in the U.S. (named ERADICATE Hp). 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.:
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 drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-102 -** a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting in advanced stages of development for multiple indications, with a Phase III study for an undisclosed indication planned to commence in the third quarter of 2014 and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting planned for the third quarter of 2014; (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON®** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RHB-103 -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned for the third quarter of 2014; and (viii) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol. 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 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 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; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi)

competitive companies, technologies and the Company's industry. 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, 2014. 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.

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

IR contact (U.S.):
Lauren Kwiecinski
Senior Associate The Trout Group
+1-646-378-2934
lkwiecinski@troutgroup.com