RedHill Biopharma

Press Release

RedHill Biopharma Announces Completion of Patient Enrollment in a Phase III Study of RHB-105 for *H. pylori* Infection

- **The last patient has been enrolled in the ERADICATE Hp study - a randomized, placebo-controlled, first Phase III study evaluating RHB-105 as a first-line therapy for *H. pylori* bacterial infection, a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and MALT lymphoma**

- **Top-line results from the Phase III study are expected in mid-end June 2015. The primary endpoint of the study is superiority over historical standard of care efficacy levels of 70% effectiveness**

- **RHB-105 targets a significantly broader indication than existing *H. pylori* therapies, as a first line treatment of *H. pylori* infection regardless of ulcer status, with the U.S. market for *H. pylori* eradication therapies estimated at approximately $1-1.5 billion annually**

- **RHB-105 has been granted a QIDP designation by the FDA under the GAIN Act, thus benefiting from Fast-Track development status, Priority Review of a potential New Drug Application (NDA) and additional five years of exclusivity, for a total of 8 years of market exclusivity**

TEL-AVIV, Israel, April 27, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that the last patient has been enrolled in the first Phase III clinical study of RHB-105 for the treatment of *Helicobacter pylori* (*H. pylori*) bacterial infection. Top-line results from the Phase III study are expected in mid-end June 2015.

The randomized, placebo-controlled, Phase III study (the ERADICATE Hp study) is intended to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* bacterial infection, a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. The Phase III study follows a successful Phase II study conducted with the RHB-105 combination in Australia which demonstrated eradication rates exceeding 90% in 130 subjects who had previously failed standard of care therapy. The ERADICATE Hp Phase III study is planned to be followed, if successful, by a second Phase III study, and additional studies may be required subject to FDA feedback.

A total of 118 non-investigated dyspepsia patients with confirmed *H. pylori* infection were enrolled in the study, which was conducted in 13 clinical sites in the U.S. Subjects were randomized in a 2:1 ratio to receive either RHB-105 or placebo for a period of 14 days, and assessed for eradication of *H. pylori* infection 28 to 35 days after completion of treatment. The primary endpoint of the study is to show superiority in eradication of *H. pylori* infection over historical standard of care efficacy levels of 70% effectiveness.

Gilead Raday, RedHill's Senior VP Corporate and Product Development, said: "We are very excited to have completed patient enrollment for this Phase III study of RHB-105 and look forward to receiving top-line results from the study in mid-end June 2015. *H. pylori* bacteria is a major cause of gastric cancer, peptic ulcers diseases and many other conditions. The growing resistance of this bacteria to existing antibiotic therapies poses a significant challenge to patients and health organizations worldwide. The antibiotics in the RHB-105 oral capsule were specifically selected due to their potential for high effectiveness in eradicating *H. pylori*, including strains resistant to standard antibiotics, as demonstrated in a successful Phase II study. We hope that positive results in this Phase III study will help us design the next study and bring us closer to offering patients and physicians a new and effective first-line treatment for *H. pylori* eradication."

With RHB-105, RedHill is pursuing an indication of first line treatment of *H. pylori* infection regardless of ulcer status, a significantly broader indication than current standard treatments for *H. pylori,* which are typically limited and indicated to treat patients with an active or recent history of ulcers. If approved, RHB-105 may be the first *H. pylori* eradication therapy to target this broader indication, which would significantly expand the potential patient population on the label for this drug.

In November 2014, the U.S Food and Drug Administration (FDA) designated RHB-105 as a Qualified Infectious Disease Product (QIDP) under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, which is intended to encourage new antibiotic drugs for the treatment of serious or life-threatening infections. The designation allows RedHill to benefit from Fast-Track development status for RHB-105, providing for an expedited development pathway as well as

Priority Review status, potentially leading to a shorter review time by the FDA of a New Drug Application (NDA), if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period, for a total of 8 years of market exclusivity.

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, and the potential 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 oral 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) planned to be followed, if successful, by a second Phase III study. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing for a Fast Track development pathway as well as Priority Review status, potentially leading to a shorter review time by the FDA of a New Drug Application (NDA), if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period, for a total of 8 years of market exclusivity.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing first Phase III study; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **ABC294640** – a Phase II-stage orally-administered SK2 inhibitor targeting multiple inflammatory-GI diseases and related oncology indications; (vi) **MESUPRON® -** a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vii) **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; (viii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

[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.

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 research, manufacturing, 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, approvals and feedback; (iv) the manufacturing, 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 research, 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 (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 26, 2015. 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.):
Marcy Nanus
Senior Vice President
The Trout Group
+1-646-378-2927
Mnanus@troutgroup.com