Press Release

RedHill Biopharma Reports Successful Final Results of Phase III Study with RHB-105 for *H. pylori* Infection

- **The RHB-105 first Phase III Clinical Study Report demonstrates the efficacy and safety of RHB-105 in eradication of *H. pylori* infection, supports the potential superior efficacy of RHB-105 over current standard-of-care therapies and confirms the positive top-line results previously announced**

- **A meeting with the FDA is scheduled for April 2016 to discuss the confirmatory Phase III study with RHB-105, planned to be initiated in Q3/2016, and the path for approval of RHB-105 as a potential best-in-class, first-line therapy for *H. pylori* infection**

- **RHB-105 has received FDA QIDP designation under the GAIN Act, including Fast-Track development, Priority Review and extended market exclusivity for a total of eight years**

- **The 2015 global and U.S. market potential for *H. pylori* eradication therapies were estimated at approximately $4.83 billion and $1.45 billion, respectively**

TEL-AVIV, Israel, March 8, 2016 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced successful final results from the first Phase III clinical study with RHB-105 for the eradication of *H. pylori* (the ERADICATE Hp study).

The Phase III Clinical Study Report (CSR) confirms the positive top-line results previously announced by the Company. The study successfully met its primary endpoint of superiority over historical standard-of-care (SoC) eradication rate levels of 70%, with high statistical significance ($p<0.001$). The final results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105 in all patients who received at least one dose of

randomized study treatment and underwent a ^{13}C UBT test of cure at Visit 4, 28-35 days after completion of treatment with RHB-105. Subsequent open-label treatment of patients in the placebo arm with SoC therapy for persistent *H. pylori* infection demonstrated a 63% eradication rate with SoC, further supporting the potential superior efficacy of RHB-105 over SoC.

The safety profile of RHB-105 was consistent with that observed in the top-line analysis of the Phase III study. RHB-105 was shown to be safe and well-tolerated, with the majority of treatment-related adverse events assessed as mild to moderate. Only one serious adverse event was recorded in the RHB-105 treatment group and was assessed as unrelated to the study drug. The adverse event profile, laboratory values, and other safety assessments did not indicate safety concerns with respect to the use of RHB-105 in the study patient population. Pharmacokinetics samples were collected during the study and a stand-alone PK report will be generated when data analysis is complete.

A meeting with the FDA is scheduled for April 2016 to discuss the planned confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection. RedHill intends to initiate the confirmatory Phase III study in the third quarter of 2016, subject to regulatory and other approvals.

The randomized, placebo-controlled, ERADICATE Hp Phase III study was intended to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* bacterial infection. A total of 118 non-investigated dyspepsia patients with confirmed *H. pylori* infection were enrolled and treated in the study, which was conducted in the U.S. Subjects were randomized in a 2:1 ratio to receive either RHB-105 or a placebo for a period of 14 days and assessed for the eradication of *H. pylori* infection. Subsequent to completion of the treatment period and the un-blinding of the study, subjects enrolled in the placebo arm were entitled to receive SoC therapy as prescribed by the treating physician in an open-label setting, and were assessed for the eradication of *H. pylori* infection 28-35 days after completion of treatment. David Graham, M.D., M.A.C.G., of the Baylor College of Medicine, a key opinion leader in the field of gastric cancer and *H. pylori* infection, served as Principal Investigator of the ERADICATE Hp Phase III study.

Gilead Raday, RedHill's Senior VP Corporate and Product Development, said: "We are very pleased that the final results from the successful first Phase III study with RHB-105 for *H. pylori* eradication confirmed the positive top-line results previously announced. The final results further support the potential superior efficacy of RHB-105 over current standard-of-care therapies for *H. pylori* and showed RHB-105 to be safe and well-tolerated. We look forward to meeting with the FDA in April to present the Clinical Study Report and discuss the path to potential approval and the intended design for the confirmatory Phase III study with RHB-105, which we plan to initiate during the third quarter of the year. We continue to work diligently to bring RHB-105 to the market as soon as possible as a best-in-class, first-line therapy for eradication of *H. pylori*."

RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing 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, in addition to the standard exclusivity period, for a total of 8 years of market exclusivity.

The 2015 global and U.S. market potential for *H. pylori* eradication therapies, at current branded prices, were recently estimated at approximately $4.83 billion and $1.45 billion, respectively, and could potentially grow with increasing awareness of the health risks associated with *H. pylori* infection and the benefits of its eradication[1].

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 indicated only for patients with active or recent history of duodenal ulcer disease. 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 for this drug candidate.

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 the 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. A first Phase III study with RHB-105 was completed in the U.S. with positive results (the ERADICATE Hp study). The study demonstrated an overall success rate of 89.4% in eradicating *H. pylori*, and met its protocol-defined primary endpoint of superiority in eradication of *H. pylori* infection over historical standard of care efficacy levels of 70%, with high statistical significance ($p<0.001$). RedHill plans to conduct a confirmatory Phase III study. Additional studies may be required, subject to FDA feedback. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as Priority Review status, potentially leading to a shorter review time by the FDA of an NDA, if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity, in addition to the standard exclusivity period, for a total of 8 years of market exclusivity.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of

[1] Jerry Rosenblatt, Ph.D., a member of RedHill's Advisory Board and Partner at Foster Rosenblatt, RedHill Biopharma press release: *RedHill Biopharma's Investor Webcast Forum Provides Update on the RHB-105 Phase III Program and Potential H. Pylori Eradication Market*, May 18, 2015.

inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a 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 and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a planned Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class 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 discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) 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 25, 2016. 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