Press Release

RedHill Biopharma Successfully Meets Primary Endpoint in Phase III Study of RHB-105 for *H. pylori* Infection

- **Top-line results from the RHB-105 Phase III study demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105**
- **The Phase III study successfully met its primary endpoint of superiority over historical standard of care efficacy levels of 70%, with high statistical significance (p<0.001); No serious adverse events or unexpected safety issues identified**
- **A meeting with FDA is being planned by RedHill to discuss the clinical and regulatory path for approval of RHB-105 as a potential best-in-class, first-line therapy for *H. pylori* infection, a major cause of gastric diseases, gastric cancer and MALT lymphoma**
- **RHB-105 received FDA QIDP designation under the GAIN Act for serious or life-threatening infections, including Fast-Track development, Priority Review and extended market exclusivity for a total of 8 years**
- **The 2015 global and U.S. market potential for *H. pylori* eradication therapies are estimated at approximately $4.83 billion and $1.45 billion, respectively**
- **RedHill will host a conference call to discuss the Phase III top-line results today, June 15, 2015, at 8:30 a.m. EDT**

TEL-AVIV, Israel, June 15, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced positive top-line results from its Phase III study with RHB-105 for the treatment of *Helicobacter pylori* (*H. pylori*) bacterial infection.

Top-line results from the study demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105.

The ERADICATE Hp first Phase III study successfully met its primary endpoint of superiority over historical standard of care efficacy levels of 70%, with high statistical significance ($p < 0.001$). No serious adverse events, new or unexpected safety issues were noted in the study.

The top-line results from the RHB-105 Phase III study, demonstrating achievement of primary endpoint, were provided to RedHill by an independent third party following an independent analysis and remain subject to completion of the independent review and analysis of the underlying data, including all safety, secondary and other outcome measures, and completion of the clinical study report (CSR), expected in the third quarter of 2015.

Prof. 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 and Principal Investigator of the ERADICATE Hp study, said: "The outstanding results of the RHB-105 Phase III study, which demonstrated a 89.4% cure rate of *H. pylori*, are consistent with the hypothesis that this may represent a promise for a new and improved treatment for *H. pylori* infection, and could significantly contribute to the prevention of gastric cancer, MALT lymphoma and other gastrointestinal diseases and conditions. Given the current high levels of antibiotic resistance and treatment failures with current standard of care therapies, RHB-105 could become, if approved, a best-in-class treatment, improving and potentially saving patients' lives."

Ira Kalfus, M.D., RedHill's Medical Director, added: "On the basis of the clear success of the ERADICATE Hp study, and the Fast-Track designation of RHB-105, we look forward to meeting with FDA to discuss the clinical and regulatory path towards marketing approval in the U.S. No new or unexpected safety issues were identified. Efficacy and safety data from this study will be submitted for presentation at an upcoming medical meeting."

Gilead Raday, RedHill's Senior VP Corporate and Product Development, said: "We are enthusiastic about the strong Phase III top-line results of RHB-105 and its potential benefit to patients. Coupled with the QIDP designation, patent protection and expanded indication, RHB-105 should be well-positioned, if approved, for commercial success as a first-line therapy for the treatment of *H. pylori* infection. We would like to thank the patients, investigators and service providers who participated in this study".

The randomized, placebo-controlled, ERADICATE Hp Phase III study was designed to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* infection. A total of 118 dyspepsia patients with confirmed *H. pylori* infection were enrolled and treated in the ERADICATE Hp 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 a placebo, for a period of 14 days, and assessed for the eradication of *H. pylori* infection 28 to 35 days after completion of treatment and for the protocol-defined primary endpoint of superiority over historical standard of care efficacy levels of 70%.

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 - a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. Gastric cancer is the second most common cause of cancer deaths worldwide with approximately 1 million deaths per year, of which 95% are caused by *H. pylori* and may be preventable. Several countries have already started, or are planning, population-based *H. pylori* screening and treatment programs designed to eliminate gastric cancer[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 in 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. The ERADICATE Hp Phase III study is planned to be followed by a second Phase III study and additional studies may be required, subject to FDA feedback.

RHB-105 was designated by the FDA as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act, which is intended to incentivize the development of 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 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, was 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[2].

RedHill will host two conference calls, in English and in Hebrew, to review the top-line results of the RHB-105 ERADICATE Hp Phase III study. Please visit the Company's website for dial-in information and webcast access: http://ir.redhillbio.com/events.cfm

The English conference call will be held **today, June 15, 2015, at 8:30 a.m. EDT (15:30 Israel time)**

The Hebrew conference call will be held **Tuesday, June 16, 2015, at 10:00 a.m. Israel time.**

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[1] Prof. David Graham, Principal Investigator of the ERADICATE Hp study, RedHill Biopharma RHB-105 Investor Webcast Forum, May 14, 2015.

[2] 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.

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 is ongoing in the U.S. with positive top-line 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 second 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, 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 of late clinical-stage, proprietary, orally-administered, small molecule 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 successful top-line 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; (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 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.

The top-line results from the Company's ERADICATE Hp study are preliminary in nature, as they are based solely on top-line information provided to the Company by an independent third-party contractor. The Company intends to examine the data from this study in greater detail, along with all of the information gathered during this study, including all safety, secondary and outcome measures. Such analysis may result in findings inconsistent with the top-line data disclosed in this release. As such, investors should not rely on the top-line results reported in this release as the final definitive results of the ERADICATE Hp study. Once the Company has fully analyzed the results

the ERADICATE Hp study, including the clinical study report, it will issue a release with the definitive findings.

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.

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