Press Release

RedHill Biopharma Announces First Dosing in RHB-105 Supportive PK Studies Ahead of Confirmatory Phase III Study for *H. pylori* Infection

- **The first group of subjects have been dosed in a single-dose three-way crossover pharmacokinetic (PK) study with RHB-105 versus the active comparators in the confirmatory Phase III study and in a food-effect study with RHB-105 in healthy volunteers**

- **The confirmatory Phase III study with RHB-105 for *H. pylori* infection is planned to be initiated, subject to regulatory approvals and completion of the supportive PK program, by April of this year**

- **Subject to a successful outcome, the confirmatory Phase III study and the supportive PK program are expected to complete the package required for a U.S. NDA for RHB-105**

- **The first Phase III study with RHB-105 successfully demonstrated 89.4% efficacy in eradicating *H. pylori* infection (p<0.001), supporting the potential superior efficacy of RHB-105 over current standard-of-care (SoC) therapies**

- **RHB-105 was granted QIDP designation by the FDA under the GAIN Act, including Fast-Track development, NDA Priority Review and extended U.S. market exclusivity, for a total of eight years**

- ***H. pylori* bacterial infection is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa-associated lymphoid tissue (MALT) lymphoma and is estimated to affect over half of the adult population worldwide**

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

TEL-AVIV, Israel, January 10, 2017 RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily

focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today announced first dosing in a three-way crossover pharmacokinetic (PK) study with RHB-105 in 18 subjects (healthy volunteers), intended to evaluate the bioavailability (BA) of RHB-105 actives versus the comparator in the planned confirmatory Phase III study (dual therapy of amoxicillin and omeprazole) and a food-effect study with RHB-105.

These PK studies are intended to support the planned confirmatory Phase III study with RHB-105, a proprietary, fixed-dose, oral combination therapy for the eradication of *H. pylori* infection.

The two-arm, randomized, double-blind, active comparator confirmatory Phase III study, comparing RHB-105 against a dual therapy amoxicillin and omeprazole regimen at equivalent doses, is planned to be initiated by April of 2017, after completion of the ongoing supportive PK program and submission of clinical study reports to the FDA. The confirmatory Phase III study is planned to enroll approximately 440 patients in up to 55 clinical sites in the U.S.

The planned confirmatory Phase III study, along with the results from the successfully completed first Phase III study with RHB-105 (the ERADICATE Hp study) and data to be obtained from the ongoing supportive PK program, are expected to support a U.S. New Drug Application (NDA) for RHB-105.

The ERADICATE Hp first Phase III study with RHB-105 successfully met its protocol-defined mITT primary endpoint of superiority over historical standard-of-care (SoC) eradication rate of 70%, with high statistical significance ($p<0.001$). The study results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105. Notably, the 89.4% efficacy in eradicating *H. pylori* infection with RHB-105 was also superior to subsequent open-label treatment with SoC therapies of patients in the placebo arm of the ERADICATE Hp study, which demonstrated only 63% eradication rate in the mITT population ($p=0.006$), further supporting the potential efficacy of RHB-105 as a treatment for *H. pylori* infection. Treatment with RHB-105 appeared to be safe and well tolerated.

RHB-105 was granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as NDA Priority Review status, potentially leading to a shorter NDA review time by the FDA, if filed. If approved, RHB-105 is entitled, thanks to its QIDP status, to receive an additional five years of U.S. market exclusivity, in addition to the standard exclusivity period, for a total of 8 years of U.S. market exclusivity.

RedHill is pursuing with RHB-105 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 in the U.S. to target this broader indication, which would significantly expand the potential patient population for this drug candidate.

H. pylori bacterial infection is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa-associated lymphoid tissue (MALT) lymphoma. *H. pylori* infection is estimated to affect over half of the adult population worldwide. The growing resistance of the *H. pylori* bacteria to metronidazole and clarithromycin has resulted in increasing failure rates of current SoC for *H. pylori* eradication, reaching an estimated 30%[1]. Despite the strong unmet medical need, no new drug has been approved by the FDA for this indication in over a decade.

The 2015 global and U.S. market potential for *H. pylori* eradication therapies at current branded prices, were 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].

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 ($p<0.001$). A confirmatory Phase III study is planned to be initiated in the U.S by April 2017. Additional studies may be required, subject to FDA review. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as NDA Priority Review status, potentially leading to a shorter NDA review time by the FDA, if filed. If approved, RHB-105 will also receive an additional five years of exclusivity, in addition to the standard exclusivity period, for a total of 8 years of U.S. market exclusivity.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a specialty 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 gastrointestinal and inflammatory diseases and cancer. RedHill has a U.S. co-promotion agreement with Concordia for **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis. RedHill's clinical-stage pipeline 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 a completed proof-

[1] Malfertheiner P. *et al.* Management of *Helicobacter pylori* infection - the Maastricht IV/ Florence Consensus Report, Gut 2012;61:646-664.

[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.

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 for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA® (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON -** a Phase II-stage first-in-class, orally-administered uPA inhibitor, targeting gastrointestinal and other solid tumors and (vii) **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. More information about the Company is available at: 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 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.

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