Press Release

RedHill Biopharma Announces Final Patient Assessed in Confirmatory Phase III Study with TALICIA® for *H. pylori* Infection

- **RedHill will host an Analyst and Investor Webcast on TALICIA® for *H. pylori* infection on Tuesday, October 30, 2018, at 8:30 a.m. EDT**
- **Final patient assessed for primary endpoint, with top-line results expected before year-end 2018**
- **If successful, RedHill plans to file a U.S. NDA in early 2019 for TALICIA®, which has FDA Fast-Track designation and an expected six-months priority review**
- **Current standard-of-care therapies fail in approximately 30% of patients due to increasing antibiotic resistance**
- **TALICIA® showed significant superiority (p<0.001) over historical standard-of-care efficacy rates in its first Phase III study**
- **2018 U.S. market for *H. pylori* eradication therapies is estimated at approximately $1.4 billion**

TEL-AVIV, Israel and RALEIGH, N.C., October 24, 2018 -- RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal diseases, today announced that the final patient was assessed for primary endpoint in the confirmatory Phase III study with TALICIA® (RHB-105)[1] for *H. pylori* infection (ERADICATE Hp2 study).

[1] TALICIA® (RHB-105) is an investigational new drug, not available for commercial distribution.

Top-line results from the ERADICATE Hp2 study are expected to be announced before year-end 2018. Subject to a successful outcome and additional regulatory feedback, RedHill plans to file a U.S. New Drug Application (NDA) with the Food and Drug Administration (FDA) for TALICIA® in early 2019, with an expected six-months priority review period. TALICIA® was granted Qualified Infectious Disease Product (QIDP) designation and Fast-Track development designation by the FDA, including a total of eight years of U.S. market exclusivity.

"Treatment of *H. pylori* has become more difficult due to increasing resistance to the antibiotics used in current standard-of-care therapies, leading to approximately 30% treatment failure rate. Considering the well-established causal relationship between *H. pylori* infection and serious conditions such as gastric cancer, both the FDA and the World Health Organization have recognized the urgent need for more effective therapies to eradicate *H. pylori*," **stated Ira Kalfus, MD, RedHill's Medical Director**. "TALICIA® showed significant superiority over historical standard-of-care efficacy rates of 70% in its first Phase III study ($p<0.001$). The results were also superior to subsequent open-label treatment with standard-of-care therapies of patients in the placebo arm, which demonstrated 63% eradication rate ($p=0.006$). If approved, TALICIA® could become a first-line, on-label treatment for eradication of *H. pylori* infection regardless of ulcer status and provide physicians and patients with a new best-in-class therapy with little to no *H. pylori* resistance, addressing the urgent need for new therapies for this highly prevalent infection."

The ERADICATE Hp2 confirmatory Phase III study is a two-arm, randomized, double-blind, active-comparator, confirmatory Phase III study which compares TALICIA® against a dual therapy amoxicillin and omeprazole regimen at equivalent doses. The study investigated 455 dyspepsia patients with confirmed *H. pylori* infection at 55 clinical sites across the U.S. Subjects were randomized 1:1 to receive four capsules, three times daily, of either TALICIA® or the active comparator, for a period of 14 days. Subjects were assessed for the study's primary endpoint of eradication of *H. pylori* infection at least 43 days after initiation of treatment. The study is 90% powered to detect a 13% treatment effect (active arm 83% vs. control arm 70%).

Analyst and Investor Webcast on TALICIA® for *H. pylori* infection:

Ahead of the ERADICATE Hp2 study top-line results, RedHill will host an analyst and investor webcast on TALICIA® for *H. pylori* infection on Tuesday, October 30, 2018, at 8:30 a.m. EDT.

Members of RedHill's executive team will be joined by the study's lead investigator and key opinion leader, Professor David Y. Graham, M.D., M.A.C.G., and will discuss TALICIA®, the ERADICATE Hp2 study, *H. pylori* infection, the current treatment landscape and potential market. A question and answer session will be held following the presentations.

The conference call**,** including a slide presentation, will be broadcast live and available for replay for 30 days on the Company's website, http://ir.redhillbio.com/events. Please access the website at least 15 minutes ahead of the conference call to register.

Participants who wish to ask questions during the event can do so by dialing in to the event. To participate in the conference call, please dial one of the following numbers 5-10 minutes prior to the start of the call: United States: +1-800-458-4121; International: +1-929-477-0324; and Israel: +972-3-376-1315. The access code for the call is: 5774327.

About TALICIA®:
TALICIA® is a novel and proprietary fixed-dose, all-in-one oral capsule combination of two antibiotics, rifabutin and amoxicillin, and a proton pump inhibitor (PPI), omeprazole.

The first Phase III study with TALICIA® (ERADICATE Hp study) successfully met its 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 TALICIA®. Notably, these results were also superior to subsequent open-label treatment with SoC therapies of patients in the placebo arm of the ERADICATE Hp study, which demonstrated 63% eradication rate ($p=0.006$), further supporting the potential efficacy of TALICIA®. Treatment with TALICIA® was shown to be safe and well tolerated and eliminates concerns of resistance to current SoC.

About *H. pylori*:
H. pylori bacterial infection affects over 50% of the adult population worldwide[2] and 30-40% of the U.S. population[3], with an estimated three million patients treated annually in the U.S. *H. pylori* is classified as a group I carcinogen by the International Agency for Research on Cancer. It is the strongest risk factor for the development of gastric cancer[2] and a major risk factor for peptic ulcer disease, and gastric mucosa-associated lymphoid tissues (MALT) lymphoma[4]. Eradication of *H. pylori* is becoming more difficult; current standard-of-care therapies fail in approximately 30% of patients, who remain *H. pylori* positive, due to increasing resistance of *H. pylori* to antibiotics commonly used in standard combination therapies[5]. Clarithromycin-resistant *H. pylori* was formally categorized by the World Health Organization as a pathogen for which there is a high priority need to develop new treatments[6].

The 2018 global market for *H. pylori* eradication therapies is estimated at approximately $4.8 billion, of which $1.4 billion is from the U.S.[7]

The ERADICATE Hp2 confirmatory Phase III study with TALICIA® (RHB-105) is registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institutes of Health

[2] Lamb A et al. *Role of the Helicobacter pylori-induced inflammatory response in the development of gastric cancer.* J Cell Biochem 2013 Mar; 114(3):491-7
[3] Chey WD et al. *Management of Helicobacter pylori Infection.* Am J Gastroenterol 2007;102:1808–1825
[4] NIH – *Helicobacter pylori* and Cancer, September 2013.
[5] Malfertheiner P. et al. *Management of Helicobacter pylori infection - the Maastricht IV/ Florence Consensus Report,* Gut 2012;61:646-664; Graham DY et al. *New concepts of resistance in the treatment of Helicobacter pylori infections.* Nat Clin Pract Gastroenterol Hepatol. 2008 Jun;5(6):321-31 and Graham DY et al. Helicobacter pylori treatment in the era of increasing antibiotic resistance. Gut 2010;59:1143-1153
[6] http://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed
[7] Foster Rosenblatt market analysis, October 2018

(NIH), which provides access to information on publicly and privately supported clinical studies.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes four gastrointestinal products in the U.S.: **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi®** - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg -** a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions, and **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104,** with positive top-line results from a first Phase III study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102),** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (v) **YELIVA® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107 (formerly MESUPRON),** a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.

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, the risk that top-line results of the confirmatory Phase III study with TALICIA® for H. pylori infection will be later than expected, the risk that the potential filing of a U.S. NDA for TALICIA® and potential FDA approval of TALICIA® will be later than expected or will not occur at all or that worldwide or U.S. markets for H. pylori eradication therapies will not reach the amounts currently estimated and other 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 successfully promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam®; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) 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; (viii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other companies and technologies within 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 22, 2018. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise, unless required by law.

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