Press Release

RedHill Biopharma Enrolls 400th Patient in Confirmatory Phase III Study with TALICIA® for *H. pylori* Infection

- **400 of the planned total of 444 patients have been enrolled in the ongoing confirmatory U.S. Phase III study with TALICIA® for *H. pylori* infection (ERADICATE Hp2)**
- **RedHill expects to complete enrollment in the Phase III ERADICATE Hp2 study in coming weeks and announce top-line results in Q4/2018**
- **If successful, and subject to additional regulatory feedback, the study is expected to complete the package required for filing a U.S. NDA for TALICIA® in early 2019**
- **TALICIA® is intended to be the first product indicated for the treatment of *H. pylori* infection in adults, regardless of ulcer status**
- **TALICIA® was granted QIDP designation by the FDA, providing eligibility for Fast-Track Development, priority NDA review and extended U.S. market exclusivity for a total of eight years**

TEL-AVIV, Israel / RALEIGH, N.C., July 24, 2018 -- RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal diseases, today announced that it has enrolled 400 of the planned total of 444 patients in the ongoing confirmatory Phase III study investigating TALICIA® (RHB-105)[1] for *H. pylori* infection (ERADICATE Hp2).

"RedHill is on track to complete enrollment of the ERADICATE Hp2 study in the coming weeks, and we expect to announce top-line results in the fourth quarter of this year," said Dror Ben-Asher, RedHill's Chief Executive Officer. "If successful, we anticipate this study to complete the package required to file a U.S. NDA for TALICIA®, intended to be the first product indicated for the treatment of *H. pylori* infection in adults, regardless of ulcer status.

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

With a planned NDA filing in early 2019, the FDA could potentially approve TALICIA® in the second half of 2019 following a priority review."

The two-arm, randomized, double-blind, active comparator, ERADICATE Hp2 confirmatory Phase III study is designed to enroll 444 non-investigated dyspepsia patients with confirmed *H. pylori* infection at up to 65 clinical sites in the U.S. The primary endpoint is eradication of *H. pylori* infection at 43 through 71 days after initiation of treatment.

The first Phase III study with TALICIA® (ERADICATE Hp study) 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 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 in the mITT population ($p=0.006$), further supporting the potential efficacy of TALICIA®. Treatment with TALICIA® appeared to be safe and well tolerated.

TALICIA® was granted Qualified Infectious Disease Product (QIDP) designation by the FDA under the GAIN Act, providing eligibility for Fast-Track Development, priority New Drug Application (NDA) review of six months and extended U.S. market exclusivity for a total of eight years.

About *H. pylori*:
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[2].

2015 worldwide and U.S. markets for *H. pylori* eradication therapies were estimated at approximately $4.83 billion and $1.45 billion, respectively[3].

About TALICIA® (RHB-105):
TALICIA® (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 TALICIA® (ERADICATE Hp study) was completed in the U.S. with positive results. A confirmatory Phase III study (ERADICATE Hp2 study) is ongoing in the U.S. Additional studies may be required, subject to FDA review.

[2] Hunt, R. H., et al. "Helicobacter pylori in developing countries." World Gastroenterology Organisation Global Guidelines (2010): 1-15.
[3] Jerry Rosenblatt, Ph.D., 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.

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 (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 has rights to four commercial 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 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 an ongoing 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. 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, the risk that top-line results of the Phase III study with TALICIA® for H. pylori 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 amount 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® 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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