Press Release

RedHill Biopharma Receives FDA Orphan Drug Designation for MESUPRON for Pancreatic Cancer

- **RedHill to benefit from various incentives to develop MESUPRON (upamostat) for the adjuvant treatment of pancreatic cancer, including a seven-year marketing exclusivity period for the indication, if approved**
- **MESUPRON is a proprietary, first-in-class, orally-administered protease inhibitor, with several potential mechanisms of action to inhibit tumor invasion and metastasis**
- **Pancreatic cancer is the third leading cause of cancer mortality in the U.S. and is characterized as a disease with a very high unmet medical need**
- **The 2017 Worldwide sales of pancreatic cancer therapies are estimated to reach approximately $1.6 billion**
- **Recently identified high-affinity molecular targets suggest additional applications in inflammatory gastrointestinal diseases**

TEL-AVIV, Israel / RALEIGH, NC, October 20, 2017 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, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted MESUPRON (upamostat) Orphan Drug designation for the adjuvant treatment of pancreatic cancer.

The Orphan Drug designation allows RedHill to benefit from various development incentives to develop MESUPRON for this indication, including tax credits for qualified clinical testing, waiver of a prescription drug user fee (PDUFA fee) upon submission of a potential marketing application and, if approved, a seven-year marketing exclusivity period.

MESUPRON is a proprietary, first-in-class, orally-administered protease inhibitor, with several potential mechanisms of action to inhibit tumor invasion and metastasis. MESUPRON presents a new, non-cytotoxic approach to cancer therapy. MESUPRON has undergone several Phase I studies and two Phase II proof-of-concept studies.

RedHill recently announced the receipt of a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering the use of MESUPRON and RedHill's Phase II-stage investigational compound, YELIVA®, in combination with a known antibiotic, for hard-to-treat cancers.

Pancreatic cancer is the third leading cause of cancer mortality in the U.S.[1] and is characterized as a disease with a very high unmet medical need. The overall five-year survival rate for the disease is only 8.2% in the U.S.[2], representing one of the poorest prognoses across all cancers. The majority of pancreatic cancer cases are diagnosed late, at which point the disease is already locally advanced or metastatic[3]. Furthermore, pancreatic cancer is predominately a cancer of the elderly, with the median age of diagnosis being 71 years in the U.S.[4] It is estimated that 53,670 new cases[5] will be diagnosed in 2017 in the U.S. The 2017 worldwide sales of pancreatic cancer therapies are estimated to reach approximately $1.6 billion[6].

RedHill has an ongoing research collaboration agreement with the Department of Molecular Biology and Genetics of Aarhus University in Denmark for the evaluation of MESUPRON. With the recent identification of human trypsin-3 and human trypsin-2 as high-affinity molecular targets, RedHill is also evaluating utilization of MESUPRON in several inflammatory gastrointestinal indications.

About MESUPRON:
MESUPRON is a proprietary, first-in-class, orally-administered potent inhibitor of several proteases targeting cancer and inflammatory gastrointestinal diseases. Protease inhibitors have been shown to play key roles in tumor invasion and the metastasis process. High levels of certain proteases are associated with poor prognosis in various solid tumor cancers, such as pancreatic, gastric, breast and prostate cancers. MESUPRON presents a promising new non-cytotoxic approach to cancer therapy with several potential mechanisms of action to inhibit both tumor metastasis and growth. MESUPRON has undergone several Phase I studies and two Phase II proof-of-concept studies. The first Phase II study was in locally-advanced, unresectable pancreatic cancer and the second study in metastatic breast cancer in combination with first-line chemotherapeutic agents. RedHill recently announced the receipt of a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering the use of MESUPRON and RedHill's Phase II-stage investigational compound,

[1] American Cancer Society: https://cancerstatisticscenter.cancer.org/#!/.
[2] National Cancer Institute: https://seer.cancer.gov/statfacts/html/pancreas.html.
[3] Global Data: Pancreatic Cancer – Epidemiology Forecast to 2022 (July 2013).
[4] American Cancer Society: https://www.cancer.org/cancer/pancreatic-cancer/causes-risks-prevention/risk-factors.html.
[5] National Cancer Institute: https://seer.cancer.gov/statfacts/html/pancreas.html.
[6] GlobalData (accessed October 2017).

YELIVA®, in combination with a known antibiotic, for hard-to-treat cancers. RedHill acquired the exclusive worldwide rights to MESUPRON, excluding China, Hong Kong, Taiwan and Macao, from Germany's WILEX AG for all indications.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: 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 promotes three gastrointestinal products in the U.S. - **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, **EnteraGam®**, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools, and **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. RedHill's clinical-stage pipeline includes: (i) **TALICIA™ (RHB-105) -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study and an ongoing confirmatory Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study, a completed proof-of-concept Phase IIa study for multiple sclerosis, and a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with successful top-line results from a Phase III study in acute gastroenteritis and gastritis and successful top-line results from a Phase II study in 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 protease inhibitor, targeting pancreatic cancer and inflammatory gastrointestinal diseases 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 two EU member states under the European Decentralized Procedure (DCP). 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 successfully market Donnatal® and 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 of 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; and (xii) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xiii) the Company's Expanded Access Program, which allows patients with life-threatening diseases potential access, subject to regulatory and other approvals, to RedHill's investigational new drugs that have not yet received regulatory marketing approval, if a patient suffers an adverse experience using such investigative drug, potentially adversely affecting the clinical development program of that investigational product or the Company generally; (xiv) competitive 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 23, 2017. 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