Press Release

RedHill Biopharma Provides Update on Ongoing Phase III and Phase II studies with BEKINDA® and Expected Timing of Top-Line Results

- **Top-line results from both the ongoing Phase III clinical study for acute gastroenteritis and gastritis and the ongoing Phase II clinical study for diarrhea-predominant irritable bowel syndrome (IBS-D) are expected in mid-2017**

- **Over two-thirds of the planned total of 320 subjects have been enrolled to date in the Phase III clinical study with BEKINDA® 24 mg for acute gastroenteritis and gastritis in the U.S. (the GUARD study)**

- **Approximately half of the planned total of 120 subjects have been enrolled to date in the Phase II clinical study with BEKINDA® 12 mg for the treatment of IBS-D in the U.S.**

- **Worldwide potential market for gastroenteritis and gastritis treatments are estimated to exceed $650 million annually**

- **U.S. potential market for IBS-D treatments is estimated to exceed $1.3 billion by 2020**

TEL-AVIV, Israel, November 3, 2016 RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a 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 provided an update on its ongoing Phase III and Phase II clinical studies with BEKINDA® for the treatment of acute gastroenteritis and gastritis and for diarrhea-predominant irritable bowel syndrome (IBS-D), respectively.

BEKINDA® is a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron, targeting multiple gastrointestinal indications. A Phase III study

with BEKINDA® 24 mg for acute gastroenteritis and gastritis is ongoing in the U.S. (the GUARD study). A Phase II study with BEKINDA® 12 mg is also ongoing in the U.S. for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Top-line results from both studies are expected in mid-2017.

Acute gastroenteritis and gastritis - Phase III study

The ongoing randomized, double-blind, placebo-controlled GUARD Phase III study with BEKINDA® 24 mg for acute gastroenteritis and gastritis is being conducted at up to 30 sites in the U.S. and is enrolling adults and children over the age of 12 who suffer from acute gastroenteritis and gastritis. 226 subjects, over two-thirds of the planned total of 320 subjects, have been enrolled in the study to date, and top-line results are expected in mid-2017.

The primary endpoint for the study is the absence of vomiting and the absence of the need for rescue medications or intravenous hydration after 30 minutes and through 24 hours after the first dose of the study medication. Secondary endpoints include, among others, frequency of vomiting, severity and time to resolution of nausea and time to resumption of normal activities.

As previously announced, in light of discussions with the FDA RedHill believes that, subject to achieving highly significant positive results, the Phase III GUARD study may be sufficient as a single study to support potential future marketing applications in the U.S., conditional upon, among other things, future review and guidance from the FDA.

BEKINDA® is intended to provide patients with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet and, if approved, may also reduce the burden on health systems by reducing hospital readmissions.

According to one estimate, there are over 179 million cases of gastroenteritis and gastritis annually in the U.S. alone[1]. The worldwide potential market for gastroenteritis and gastritis treatments is estimated to exceed $650 million annually[2].

IBS-D - Phase II study

The ongoing randomized, double-blind, placebo-controlled Phase II clinical study is intended to evaluate the safety and efficacy of BEKINDA® 12 mg in adults over the age of 18 who suffer from IBS-D, at up to 16 clinical sites in the U.S. Approximately half of the total 120

[1] Wikswo, Mary E., Anita Kambhampati, Kayoko Shioda, Kelly A. Walsh, Anna Bowen, and Aron J. Hall. "Outbreaks of Acute Gastroenteritis Transmitted by Person-to-Person Contact, Environmental Contamination, and Unknown Modes of Transmission — United States, 2009–2013."Morbidity and Mortality Weekly Report (MMWR) 64(SS12) (2015): 1-16. Centers for Disease Control and Prevention, 11 Dec. 2015.

[2] Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727–741 and Company analysis.

planned subjects have been enrolled in the study to date, and top-line results are expected in mid-2017.

The primary endpoint for the study is the proportion of patients in each treatment group with response in stool consistency as compared to baseline, per FDA guidance definition. Secondary endpoints include the proportion of patients in each treatment group who are pain responders and the proportion of patients in each treatment group who are responders to the combined endpoints of stool consistency and pain, per FDA guidance definition.

IBS is one of the most common gastrointestinal disorders. It is estimated that at least 30 million Americans suffer from IBS[3], of which over 50% are cases of IBS-D[4]. The U.S. potential market for IBS-D treatments is estimated to exceed $1.3 billion by 2020[4].

5-HT3 antagonists such as ondansetron, the active pharmaceutical ingredient in BEKINDA®, have been shown to slow intestinal transit time in humans[5]. Alosetron (Lotronex®), a 5-HT3 antagonist of the same class of drugs as ondansetron, has been approved for the treatment of women with severe chronic IBS-D but is under a restricted prescribing (REMS) program due to potential severe side effects[6]. Ondansetron, approved by the FDA as an oncology support antiemetic, has demonstrated activity in IBS-D in preliminary studies[7] and, in light of its good safety profile, RedHill believes that BEKINDA®, if approved, has the potential to be a preferred once-daily treatment for a broad segment of patients suffering from IBS-D.

About BEKINDA® (RHB-102):
BEKINDA® is a proprietary, bimodal extended-release (24 hours) oral pill formulation of ondansetron covered by several issued and pending patents. A Phase III clinical study of BEKINDA® 24 mg formulation for acute gastroenteritis and gastritis (the GUARD study) is ongoing in the U.S., with top-line results expected in mid-2017. A Phase II study with BEKINDA® 12 mg formulation is ongoing in the U.S. for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D), with top-line results expected in mid-2017. RedHill is also pursuing a potential marketing approval of BEKINDA® in Europe for the

[3] Lovell RM, Ford AC, Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis, Clin Gastroenterol Hepatol (2012), 10(7)712-721; Saito YA et al, The epidemiology of irritable bowel syndrome in North America: a systemic review, Am J Gastroenterol (2002), 97(8): 1910-5.

[4] EvaluatePharma - Irritable bowel syndrome Indication Profile.

[5] Garsed K. et al, A randomised trial of ondansetron for the treatment of irritable bowel syndrome with diarrhoea, Gut (2014), 63(10): 1617-25.

[6] www.fda.gov, post market drug safety information for patients and providers.

[7] Steadman CJ et al, Selective 5-hydroxytryptamine type 3 receptor antagonism with ondansetron as treatment for diarrhea-predominant irritable bowel syndrome: a pilot study, Mayo Clin Proc (1992), 67(8):732-8; Clayton NM et al, The pharmacological properties of the novel selective 5-HT3 receptor antagonist, alosetron, and its effects on normal and perturbed small intestinal transit in the fasted rat, Neurogastroenterol (1999), 11: 207-217; Garsed K. et al, A randomised trial of ondansetron for the treatment of irritable bowel syndrome with diarrhoea, Gut (2014), 63(10): 1617-25.

prevention of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively), pending additional feedback from EU member states as to whether additional clinical and CMC work is required.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a 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's current pipeline of proprietary products 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 an ongoing proof-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; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class, orally-administered Hsp27 inhibitor, 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 discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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.

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