Press Release

RedHill Biopharma Announces Final Results from Phase II Study with BEKINDA® for IBS-D

TEL-AVIV, Israel / RALEIGH, NC, January 16, 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 and cancer, today announced top-line final results[1] from the Phase II clinical study with BEKINDA® 12 mg (RHB-102)[2] for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).

- An independent review and analysis of the final results, provided to the Company, confirmed that the Phase II study with BEKINDA® 12 mg successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). The final top-line results improve upon the previously announced top-line results (absolute difference of 19.4%, p-value=0.05).

- Results from the BEKINDA® Phase II study suggest that they compare favorably with previously reported efficacy outcome values from studies of Xifaxan® (rifaximin) and Viberzi® (eluxadoline) across all three efficacy endpoints[3].

- The randomized, double-blind, placebo-controlled Phase II study evaluated the efficacy and safety of BEKINDA® 12 mg in 126 subjects over 18 years old in the U.S., who

[1] Final top-line results remain subject to the Clinical Study Report (CSR).

[2] BEKINDA® is an investigational new drug, not available for commercial distribution.

[3] For more details see RedHill's press release dated October 3, 2017. Xifaxan® (rifaximin) prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2010/022554lbl.pdf; Viberzi® (eluxadoline) prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2015/206940s000lbl.pdf; Average absolute difference from reported Phase III studies; The theoretical comparison between the BEKINDA® 12 mg Phase II study results and reported data from studies of IBS-D-approved therapies serves as a general benchmark for the effect size observed with BEKINDA® 12 mg and should not be construed as a direct and/or equal comparison given that the studies were not identical in design, patient population and treatment period. For example, in the Xifaxan® 550 mg Phase III studies, the referenced efficacy endpoints were evaluated over a period of 4 weeks after 2 weeks drug administration, and in the Viberzi® 100 mg Phase III studies the referenced efficacy endpoints were evaluated after drug was administered and evaluated for 12 weeks. The studies were not conducted head-to head in the same patient population.

received either BEKINDA® 12 mg or placebo, once daily, for a period of eight weeks.

- IBS is one of the most common gastrointestinal disorders[4], affecting an estimated 30 million Americans, of which approximately 40% are estimated to be cases of IBS-D[5]; The U.S. market of IBS-D therapies grew by approximately 550% between 2013-2016[6].

- RedHill plans to meet with the FDA in the first half of 2018 to discuss the design for one or two pivotal Phase III studies with BEKINDA® 12 mg for 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 with BEKINDA® 24 mg for the treatment of acute gastroenteritis and gastritis (the GUARD study) successfully met its primary endpoint. A Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) also successfully met its primary endpoint.

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 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; **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) -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and successful results from a first Phase III study ; (ii) **RHB-104 -** an oral combination therapy with an ongoing first Phase III study for Crohn's disease and a planned pivotal Phase III study for nontuberculous mycobacteria infections(NTM); (iii) **YELIVA® (ABC294640) -** an orally-administered, first-in-class SK2 selective inhibitor with an ongoing Phase IIa study for cholangiocarcinoma; (iv) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with positive final results from a Phase III study in acute gastroenteritis and gastritis and positive top-line final results from a Phase II study in IBS-D; (v) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **RHB-107** (**MESUPRON) -** a Phase II-stage first-in-class, orally-administered protease inhibitor, targeting pancreatic cancer and inflammatory gastrointestinal diseases. More information about the Company is available at: www.redhillbio.com.

[4] GlobalData PharmaPoint: Irritable Bowel Syndrome – Global Drug Forecast and Market Analysis to 2023.
[5] 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.
[6] EvaluatePharma – USA sales by indication (IBS-D) (July 2017).

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 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 23, 2017. 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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