



RedHill Biopharma Announces Positive End-of-Phase II Meeting with FDA on BEKINDA® for IBS-D

September 12, 2018

- **The positive Type B meeting with the FDA followed a successful Phase II study of BEKINDA® for diarrhea-predominant irritable bowel syndrome (IBS-D), one of the most common gastrointestinal disorders**
- **In light of the clarity provided by the FDA regarding the clinical and regulatory pathway for potential approval of BEKINDA®, RedHill plans to finalize the design of two pivotal Phase III studies with BEKINDA® and to accelerate global pharma partnership discussions including U.S. co-promotion opportunities**
- **BEKINDA® also concluded a positive Phase III study (the GUARD study) for acute gastroenteritis and gastritis**

TEL-AVIV, Israel and RALEIGH, N.C., Sept. 12, 2018 (GLOBE NEWSWIRE) -- [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 it recently concluded a positive End-of-Phase II/Pre-Phase III (Type B) meeting with the U.S. Food and Drug Administration (FDA) discussing the clinical and regulatory pathway towards potential U.S. approval of BEKINDA® (RHB-102)¹ for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).

In light of the clarity provided by the FDA, RedHill plans to finalize the design of two pivotal Phase III studies with BEKINDA® and to accelerate global pharma partnership discussions, including U.S. co-promotion opportunities.

The FDA meeting followed the positive results of the randomized, double-blind, placebo-controlled Phase II study with BEKINDA® for IBS-D. The study, which was conducted in the U.S. and enrolled 126 subjects, successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency response (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo ($p = 0.036$). Results from the 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 endpoints².

Gilead Raday, RedHill's chief operating officer, said: "We are very pleased with the outcome of our meeting with the FDA, which provided clarity on the planned endpoints as well as other important aspects for the design of the pivotal Phase III studies to support potential NDA filing. We believe BEKINDA® could become a leading safe and effective therapy for IBS-D patients and plan to accelerate global pharma partnership discussions, including U.S. co-promotion opportunities."

IBS is one of the most common gastrointestinal disorders³, affecting an estimated 30 million Americans, of which approximately 40% are estimated to be cases of IBS-D⁴. The U.S. market of IBS-D therapies grew by approximately 550% between 2013-2016⁵.

In addition, RedHill is currently in discussions with the FDA on the design of a confirmatory Phase III study with BEKINDA® for acute gastroenteritis, following the positive results from the first Phase III study.

About BEKINDA® (RHB-102):

BEKINDA® is a proprietary, bimodal extended-release (24 hours) oral tablet formulation of ondansetron, covered by several issued and pending patents. A positive first Phase III clinical study with BEKINDA® for the treatment of acute gastroenteritis and gastritis (the GUARD study) successfully met its primary endpoint. A positive Phase II study with BEKINDA® 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. 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 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 pulmonary 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, 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[®], Mytes[®] 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.

¹ BEKINDA[®] (RHB-102) is an investigational new drug, not available for commercial distribution.

² 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.

³ GlobalData PharmaPoint: Irritable Bowel Syndrome – Global Drug Forecast and Market Analysis to 2023.

⁴ 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.

⁵ EvaluatePharma – USA sales by indication (IBS-D) (July 2017).

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Source: RedHill Biopharma Ltd.