April 24, 2017

RedHill Biopharma Announces Enrollment of Last Patient in the BEKINDA® Phase II Study for IBS-D

- **Top-line results are expected in the third quarter of 2017**
- **The randomized, double-blind, placebo-controlled Phase II study is evaluating the safety and efficacy of BEKINDA® (RHB-102) 12 mg in 127 U.S. patients with diarrhea-predominant irritable bowel syndrome (IBS-D)**
- **IBS is one of the most common gastrointestinal disorders; it is estimated that at least 30 million Americans suffer from IBS, of which over 40% are cases of IBS-D**
- **If approved, BEKINDA® 12 mg has the potential to be a preferred once-daily treatment for a broad segment of patients suffering from IBS-D, targeting a U.S. potential market estimated to exceed $1 billion by 2022**
- **Top-line results from a Phase III study with BEKINDA® 24 mg for acute gastroenteritis and gastritis (the GUARD study) are expected in the second quarter of 2017**
- **RedHill will host an R&D Day and live webcast on BEKINDA® on Thursday, April 27, 2017 in NYC, discussing the product, indications, potential markets and the ongoing Phase III and II studies for acute gastroenteritis and IBS-D, respectively**

TEL-AVIV, Israel, April 24, 2017 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty 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 announced enrollment of the last patient in the Phase II study with BEKINDA® (RHB-102)[1] 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).

BEKINDA® is a proprietary, bimodal extended-release, once-daily oral pill formulation of ondansetron, targeting several gastrointestinal indications.

The randomized, double-blind, placebo-controlled Phase II study is evaluating the safety and efficacy of BEKINDA® 12 mg in adults over the age of 18 with IBS-D. The study enrolled 127 subjects in 16 U.S. clinical sites. Top-line results are expected in the third quarter of 2017.

Subjects enrolled in the Phase II IBS-D study were randomized 60:40 to receive either BEKINDA® 12 mg or a placebo, once daily, for a period of eight weeks. 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[2]. It is estimated that at least 30 million Americans suffer from IBS[3], of which over 40% are cases of IBS-D[4]. The U.S. potential market for IBS-D treatments is estimated to exceed $1 billion by 2022[5].

5-HT3 antagonists such as ondansetron, the active pharmaceutical ingredient in BEKINDA®, have been shown to slow intestinal transit time in humans[6]. Alosetron (Lotronex®), a 5-HT3 antagonist of the same class of drugs as ondansetron, has been approved by the FDA for the treatment of women with severe chronic IBS-D, but is under a restricted prescribing (REMS) program due to potential severe side effects[7]. Ondansetron, approved by the FDA as an oncology support antiemetic, has demonstrated activity in IBS-D in preliminary studies[8] and, in light of its 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.

Top-line results from the Phase III study with BEKINDA® 24 mg for acute gastroenteritis and gastritis (the GUARD study) are expected in the second quarter of 2017. In February 2017, RedHill announced that the last patient had completed the treatment course and observation period in the randomized, double-blind, placebo-controlled GUARD study, which treated 320 adults and children over the age of 12 in 29 U.S. clinical sites.

The Phase II study and the Phase III GUARD study with BEKINDA® are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

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 patient treatment course and observation period completed and top-line results expected in the second quarter of 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 patient enrollment completed and top-line results expected in the third quarter of 2017.

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 has a U.S. co-promotion agreement with Concordia for **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, as well as an exclusive license agreement with Entera Health for **EnteraGam®**, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's clinical-stage pipeline 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, a completed proof-of-concept Phase IIa study for multiple sclerosis and QIDP status for nontuberculous mycobacteria (NTM) infections; (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 protease inhibitor, targeting pancreatic cancer and other solid tumors 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) 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.

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

[2] GlobalData PharmaPoint: Irritable Bowel Syndrome - Global Drug Forecast and Market Analysis to 2023.

[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] GlobalData PharmaPoint: Irritable Bowel Syndrome - Global Drug Forecast and Market Analysis to 2023.

[5] EvaluatePharma - Irritable bowel syndrome Indication Profile.

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

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

[8] 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.

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