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RedHill Biopharma Initiates Phase II Study of BEKINDA™ for Irritable Bowel Syndrome

- **The randomized, double-blind, 2-arm parallel group Phase II study of BEKINDA™ 12 mg is expected to enroll 120 patients suffering from diarrhea-predominant irritable bowel syndrome (IBS-D) in 12 clinical sites in the U.S.**
- **The U.S. potential market for IBS-D treatments is estimated to exceed $1.3 billion by 2020**
- **A Phase III study with BEKINDA™ 24 mg for acute gastroenteritis and gastritis is ongoing in the U.S., with top-line results expected in the second half of 2016**

TEL-AVIV, Israel, April 11, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced that it has initiated a randomized, double-blind, 2-arm parallel group Phase II clinical study in the U.S. evaluating the safety and efficacy of BEKINDA™ 12 mg in patients with diarrhea-predominant irritable bowel syndrome (IBS-D).

"We are excited to initiate this study of BEKINDA™ for IBS-D, a debilitating disorder affecting millions of people worldwide with few approved therapies and a significant unmet medical need," **said Gilead Raday, RedHill's Chief Operating Officer**. "This study follows publications demonstrating that ondansetron, the active ingredient in BEKINDA™, may be an effective and safe treatment for IBS-D. We also continue to advance the Phase III GUARD study of BEKINDA™ for acute gastroenteritis and gastritis, currently ongoing in the U.S., with top-line results expected during the second half of this year."

BEKINDA™ is a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron, targeting multiple gastrointestinal indications. RedHill is pursuing clinical studies with two dose strengths of BEKINDA™, a 24 mg dose and a 12 mg dose. 5-HT3 antagonists such as ondansetron, the active pharmaceutical ingredient in BEKINDA™, have been shown to slow intestinal transit time in humans[1]. Alosetron (Lotronex®), a 5-HT3 antagonist of the same class of drugs as ondansetron, the active ingredient in BEKINDA™, 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[2]. Ondansetron, approved by the U.S. FDA as an oncology support antiemetic, has demonstrated activity in IBS-D in preliminary studies[3] 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.

The randomized, double-blind, 2-arm parallel group Phase II clinical study is designed to evaluate the safety and efficacy of BEKINDA™ 12 mg in patients suffering from IBS-D. The study is expected to be conducted in 12 clinical sites in the U.S. and to enroll 120 patients who will be 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.

Irritable bowel syndrome (IBS) is a chronic multifactorial disorder characterized by recurrent abdominal pain or discomfort associated with altered bowel function. Diarrhea-predominant irritable bowel syndrome (IBS-D) is the most common subtype of IBS in the U.S.[4] Certain factors that may alter gastrointestinal function can contribute to IBS symptoms, including stress, prior gastroenteritis and changes in the gut microbiome. However, the etiology of IBS is not well-understood and the underlying cause of IBS in many cases remains unknown. IBS negatively impacts patients' health-related quality of life and can affect patients physically, emotionally, socially and economically.

IBS is one of the most common GI disorders; it is estimated that at least 30 million Americans suffer from IBS[5], of which over

50% are cases of IBS-D4. The U.S. potential market for IBS-D treatments is estimated to exceed $1.3 billion by 2020[6].

About BEKINDA™ (RHB-102):

BEKINDA™ is a patent-protected, extended-release (24 hours) oral pill formulation of ondansetron. A Phase III clinical study of BEKINDA™ for acute gastroenteritis and gastritis (the GUARD study) is ongoing in the U.S., with top-line results expected in the second half of 2016. A Phase II study has been initiated with BEKINDA™ for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). RedHill is also pursuing marketing approval of BEKINDA™ in Europe for the 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:RDHL) (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 inflammatory and gastrointestinal diseases, including 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 in the U.S. for acute gastroenteritis and gastritis and a Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON® -** a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, 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 Hsp27 inhibitor, administered by oral tablet, 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.

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

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

[3] 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.

[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 - Irritable bowel syndrome Indication Profile

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