June 20, 2016

RedHill Biopharma Announces First Patients Dosed in Phase II Study with BEKINDA™ for IBS-D

- **The first patients have been dosed in the randomized, double-blind, placebo-controlled Phase II study with BEKINDA™ 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) in 120 subjects in 12 clinical sites in the U.S.**
- **IBS is one of the most common gastrointestinal disorders, estimated to affect at least 30 million Americans of which over 50% suffer from IBS-D**
- **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 late 2016**

TEL-AVIV, Israel, June 20, 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 and cancer, today announced that the first patients in the Phase II clinical study with BEKINDA™ 12 mg for diarrhea-predominant irritable bowel syndrome (IBS-D) have been dosed.

The randomized, double-blind, placebo-controlled Phase II clinical study is expected to enroll 120 subjects in 12 clinical sites in the U.S. and is intended to evaluate the safety and efficacy of BEKINDA™ 12 mg in patients with IBS-D.

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, for two different indications. A Phase III study of BEKINDA™ 24 mg for acute gastroenteritis and gastritis is ongoing in the U.S. (the GUARD study), with top-line results expected in late 2016.

Subjects enrolled in the Phase II study 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.

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, 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.

IBS is a chronic multifactorial disorder characterized by recurrent abdominal pain or discomfort associated with altered bowel function. Diarrhea-predominant irritable bowel syndrome 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 understood and the underlying cause of IBS remains unknown. IBS negatively impacts patients' 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-D[4]. 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 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 late 2016. 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). 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 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 in the U.S. 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 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.

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

Source: RedHill Biopharma Ltd.