October 14, 2015

RedHill Biopharma Provides Update on BEKINDA(TM) Ongoing Phase III Study for Gastroenteritis and Announces Planned Phase II Study for IBS-D

- **Based on recent U.S. FDA feedback and prior feedback from the UK MHRA, RedHill believes that the ongoing Phase III study with BEKINDA™ for gastroenteritis (the GUARD study) may be sufficient as a single study to support the filing of a marketing application in the U.S. and Europe, subject to achieving highly significant positive results**
- **In light of the FDA's guidance, the Company filed a protocol amendment to the Phase III study's approved IND to increase data collection and conduct among other things, additional safety tests**
- **RedHill plans to commence a Phase II study with BEKINDA™ for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in the fourth quarter of 2015 or the first quarter of 2016; It is estimated that at least 30 million Americans suffer from IBS, with the potential U.S. market for IBS-D estimated to exceed $1.25 billion by 2020**
- **RedHill maintains a strong and debt-free balance sheet with approximately $66 million in cash as of the end of July, supporting the ongoing Phase III GUARD study and planned IBS-D Phase II study with BEKINDA™, as well as the ongoing Phase III programs with RHB-104 for Crohn's disease, RHB-105 for *H. pylori* infection and additional development programs**

TEL-AVIV, Israel, Oct. 14, 2015 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today provided an update on its development programs with BEKINDA™ (RHB-102), a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron, targeting multiple gastrointestinal indications.

RedHill recently concluded a meeting with the U.S. FDA regarding the development path for BEKINDA™ and the ongoing randomized, double-blind, placebo-controlled, parallel group Phase III study for the treatment of acute gastroenteritis and gastritis (the GUARD study). In light of the FDA's guidance, the Company filed a protocol amendment to the Phase III study's approved IND to increase data collection and conduct among other things, additional safety tests. RedHill is also increasing the number of clinical sites in the Phase III GUARD study toup to thirty sites from the previously announced twelve sites, all of them in the U.S. With this increase in the number of sites, coupled with the seasonality of gastroenteritis, the Company expects to receive top-line results from the Phase III study in mid-late 2016.

Based on the recent feedback from the FDA, as well as prior feedback from the UK Medicines and Healthcare products Regulatory Agency (MHRA), the Company believes that, subject to achieving highly significant positive results, the expanded Phase III study for gastroenteritis and gastritis may be sufficient as a single study to support the filing of a marketing application for BEKINDA™ for this indication in both the U.S. and Europe. The potential filing of a marketing application remains conditional upon, among other things, the strength of the study's efficacy results and future review and guidance from the U.S. and European regulatory agencies once the Phase III data becomes available. If approved for marketing by the FDA, BEKINDA ™ could become the first 5-HT3 antiemetic drug indicated for the treatment of acute gastroenteritis and gastritis, targeting a potential worldwide market estimated to exceed $650 million annually[1].

RedHill further announced that it is initiating a new gastrointestinal development program with a new formulation of BEKINDA™ for the treatment of irritable bowel syndrome with diarrhea (IBS-D). A Phase II study for this indication is planned to be initiated in the fourth quarter of 2015 or the first quarter of 2016, subject to fulfillment of all regulatory requirements.

Irritable bowel syndrome (IBS) is a chronic multifactorial disorder characterized by recurrent abdominal pain or discomfort associated with altered bowel function. Irritable bowel syndrome with diarrhea (IBS-D) is the most common subtype of IBS in the U.S.[2] 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 may suffer from IBS[3], of which over 50% are cases of IBS-D[4]. The U.S. potential market for IBS-D treatments is estimated to exceed $1.25 billion by 2020.

5-HT3 antagonists such as ondansetron, the active pharmaceutical ingredient in BEKINDA™, have been shown to slow intestinal transit time in humans[5]. Alosetron (Lotronex®), a 5-HT3 antagonist, has been approved for the treatment of IBS in women with severe chronic IBS-D but is under a restricted prescribing program due to potential severe side effects[6]. Ondansetron, approved by the U.S. FDA as an oncology support antiemetic, has demonstrated activity in IBS-D in preliminary studies[7] and in light of its good safety profile RedHill believes that BEKINDA™, if approved, has the potential to be the preferred once-daily treatment for patients suffering from IBS-D.

The FDA's feedback from the recent meeting also indicated that additional clinical data is required to support a U.S. New Drug Application (NDA) with BEKINDA™ for oncology support indications under the 505(b)(2) regulatory path. Further development for oncology support indications will be decided as data from the ongoing and planned efficacy studies of BEKINDA™ for gastroenteritis and gastritis and IBS-D becomes available, and once RedHill receives additional regulatory feedback from the MHRA with regard to the European Marketing Authorization Application (MAA) that was filed in December 2014 for oncology support indications.

Gilead Raday, RedHill's Senior VP Corporate and Product Development, said: "We continue to progress the ongoing Phase III GUARD study with BEKINDA™ for gastroenteritis and expect top-line results in mid-late 2016. The productive meeting with the U.S. FDA and the subsequent amendment to the Phase III study's protocol increase our confidence that if the study has sufficiently positive results it may suffice as a single study to support the filing of an NDA in the U.S., potentially accelerating our time to market for this large opportunity. Furthermore, RedHill has prioritized the development of BEKINDA™ for gastrointestinal indications for which ondansetron has yet to be approved and where there are clear unmet medical needs as well as significant market opportunities. We will therefore focus our current efforts on the clinical development of BEKINDA™ for the indications of gastroenteritis and IBS-D, both of which may be eligible for 3 year data exclusivity from the FDA, if approved." **Mr. Raday added:** "We would like to thank the FDA for the constructive feedback during the recent meeting regarding the development path for BEKINDA™. We are excited to initiate the BEKINDA™ development program for irritable bowel syndrome with diarrhea (IBS-D), a chronic condition with a strong unmet medical need affecting tens of millions of people worldwide. RedHill maintains a strong and debt-free balance sheet with approximately $66 million in cash as of the end of July, supporting the ongoing Phase III GUARD study and planned IBS-D Phase II study with BEKINDA™, as well as the ongoing Phase III programs with RHB-104 for Crohn's disease, RHB-105 for *H. pylori* infection and additional development programs."

The GUARD Phase III study is registered on www.ClinicalTrials.gov, a web-based service by the U.S. National Institute of Health which provides public access to information on publicly and privately supported clinical studies.

About BEKINDA™ (RHB-102):

BEKINDA™ is a patent-protected, extended-release (24 hours) oral pill formulation of the active ingredient ondansetron. RedHill is developing BEKINDA™ for the treatment of acute gastroenteritis and gastritis as well as for irritable bowel syndrome with diarrhea (IBS-D) and for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively). A Phase III clinical study with BEKINDA™ for acute gastroenteritis and gastritis is ongoing in the U.S., with top-line results expected in mid-late 2016. RedHill plans to initiate a Phase II study with BEKINDA™ for the treatment of irritable bowel syndrome with diarrhea in the fourth quarter of 2015 or the first quarter of 2016. RedHill submitted in December 2014 a Marketing Authorization Application (MAA) seeking marketing approval of BEKINDA™ in Europe for the oncology support indications of CINV and RINV prevention and is awaiting further regulatory feedback.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development 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 top-line 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; (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 European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (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 a European marketing application submitted in October 2014; 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 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; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xi) competitive companies and technologies within the Company's industry; and (xii) 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 26, 2015. 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] Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727-741 and Company analysis.

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

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

[7] 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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