



February 21, 2017

## **RedHill Biopharma Completes Treatment of Last Patient in BEKINDA® Phase III Study for Acute Gastroenteritis**

- | **Top-line results are expected in the second quarter of 2017**
- | **The randomized, double-blind, placebo-controlled Phase III study is evaluating the safety and efficacy of BEKINDA® 24 mg in patients with acute gastroenteritis and gastritis (the GUARD study)**
- | **Acute gastroenteritis and gastritis are inflammations of the mucus membranes of the gastrointestinal tract which may lead to nausea, vomiting, diarrhea or abdominal pain; acute gastroenteritis is a common infectious disease, with approximately 179 million cases annually in the U.S.**
- | **If approved, BEKINDA® could become the first 5-HT3 antiemetic drug in the U.S. indicated for the treatment of acute gastroenteritis and gastritis, targeting a potential worldwide market estimated to exceed \$650 million annually**
- | **Additionally, a Phase II study with BEKINDA® 12 mg is ongoing in the U.S. for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D), with top-line results expected in mid-2017**
- | **RedHill will host an R&D Day for analysts and investors on Thursday, April 27, 2017 in NYC with live webcast on BEKINDA®, discussing the product, indications, potential markets and the ongoing Phase III and II studies for acute gastroenteritis and IBS-D, respectively**

TEL-AVIV, Israel, Feb. 21, 2017 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE: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 that the last patient enrolled in the Phase III study with BEKINDA® 24 mg for the treatment of acute gastroenteritis and gastritis (the GUARD study) has completed the treatment course and observation period for the primary endpoint evaluation.

The randomized, double-blind, placebo-controlled Phase III GUARD study with BEKINDA® 24 mg is being conducted in 29 U.S. clinical sites and has treated 320 adults and children over the age of 12 with gastroenteritis and gastritis. Top-line results are expected in the second quarter of 2017.

Robert A. Silverman, MD, MS, Emergency Medicine specialist at the Hofstra North Shore-LIJ Medical Center, and Associate Professor at the Hofstra North Shore-LIJ School of Medicine in New York, is the lead investigator for the GUARD study.

BEKINDA® is a proprietary, bimodal extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron, targeting multiple gastrointestinal indications. BEKINDA® is intended to provide patients with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet.

Following the completion of patient treatment in the Phase III study with BEKINDA® for acute gastroenteritis and gastritis and in light of the advanced stage of enrollment in the Phase II study with BEKINDA® for IBS-D, RedHill will host an R&D Day with a live webcast for analysts and investors. The event will take place on Thursday, April 27, 2017 in NYC, and will discuss BEKINDA®, its indications, potential markets and the ongoing Phase III and II studies for acute gastroenteritis and IBS-D, respectively. Additional details will be provided in the coming weeks.

The primary endpoint for the GUARD study is the absence of vomiting or the need for rescue medications or intravenous hydration from 30 minutes through 24 hours after receiving the first dose of the GUARD study drug. Secondary endpoints include, among others, frequency of vomiting, severity and time to resolution of nausea and time to resumption of normal activities.

As previously announced, in light of discussions with the U.S. Food and Drug Administration (FDA), RedHill believes that, subject to achieving highly significant positive results, the GUARD study may be sufficient as a single Phase III study to support potential future marketing application in the U.S., conditional upon, among other things, future review and guidance from the FDA.

Acute gastroenteritis and gastritis are inflammations of the mucus membranes of the gastrointestinal tract leading to a combination of symptoms which include nausea, vomiting, diarrhea or abdominal pain. Acute gastroenteritis is a common infectious disease, with approximately 179 million cases annually in the U.S.<sup>1</sup> It is caused by many different infectious agents, most commonly by viral infections, accounting for up to 70% of cases. Noroviruses cause the most outbreaks of non-bacterial acute gastroenteritis in all age groups and often occur in epidemic outbreaks in schools, nursing homes and other group settings<sup>2</sup>. Gastroenteritis and gastritis are major causes of emergency room visits, with up to 474,000 estimated hospitalizations annually in the U.S. alone<sup>3</sup>. Dehydration is the most frequent and dangerous complication of acute gastroenteritis<sup>4</sup>. Oral rehydration is the preferred therapy in mild to moderate dehydration, whereas intravenous fluids are recommended in more severe cases<sup>5</sup>. Adding ondansetron, the active ingredient in BEKINDA<sup>®</sup>, to the standard intravenous rehydration therapy has shown to significantly reduce the amount of vomiting in children with gastroenteritis<sup>6</sup>, however, to the best of RedHill's knowledge, its efficacy in adults has not been studied in a randomized clinical trial.

Ondansetron is used as an antiemetic in patients suffering from chemotherapy and radiotherapy-induced nausea and vomiting and from postoperative nausea and vomiting<sup>7</sup>. BEKINDA<sup>®</sup> may decrease the frequency of vomiting, improve the success and compliance of oral rehydration therapy and decrease the rate of intravenous therapy in patients suffering from gastroenteritis. It may also decrease the number of emergency room visits, and therefore may reduce health care costs. If approved for marketing by the FDA, BEKINDA<sup>®</sup> could become the first 5-HT<sub>3</sub> antiemetic drug in the U.S. indicated for the treatment of acute gastroenteritis and gastritis, targeting a potential worldwide market estimated to exceed \$650 million annually<sup>8</sup>.

A randomized, double-blind, placebo-controlled Phase II study with BEKINDA<sup>®</sup> 12 mg is currently ongoing in the U.S. for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The Phase II study is evaluating the safety and efficacy of BEKINDA<sup>®</sup> 12 mg in adults over the age of 18 who suffer from IBS-D at 16 clinical sites in the U.S. 100 of the planned total of 120 subjects have been enrolled to date. Top-line results are expected in mid-2017.

The Phase III GUARD study and the Phase II study with BEKINDA<sup>®</sup> are registered on [www.ClinicalTrials.gov](http://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<sup>®</sup> (RHB-102):**

BEKINDA<sup>®</sup> 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<sup>®</sup> 24 mg formulation for acute gastroenteritis and gastritis (the GUARD study) is ongoing in the U.S., with patient treatment completed and top-line results expected in the second quarter of 2017. A Phase II study with BEKINDA<sup>®</sup> 12 mg formulation is ongoing in the U.S. for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D), with top-line results expected in mid-2017.

#### **About RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE: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<sup>®</sup>**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis. 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<sup>®</sup> (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<sup>®</sup> (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 uPA inhibitor, targeting gastrointestinal and other solid tumors and (vii) **RIZAPORT<sup>®</sup> (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. More information about the Company is available at:

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.

<sup>1</sup> Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM, *Foodborne Illness Acquired in the United States - Unspecified Agents*, Emerg Infect Dis. 2011;17(1):16-22.

<sup>2</sup> Graves S. Nancy, *Acute Gastroenteritis*, Prim Care Clin Office Pract 40 (2013) 727-741.

<sup>3</sup> Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM, *Foodborne Illness Acquired in the United States - Unspecified Agents*, Emerg Infect Dis. 2011;17(1):16-22.

<sup>4</sup> Elliott, Elizabeth Jane, *Acute Gastroenteritis in Children*, BMJ, 334.7583 (2007): 35-40. PMC. Web. 8 Feb. 2017.

<sup>5</sup> Reeves JJ, Shannon MW, Fleisher GR, *Ondansetron decreases vomiting associated with acute gastroenteritis: a randomized, controlled trial*, Pediatrics. 2002;109(4):e62.

<sup>6</sup> Elliott, Elizabeth Jane, *Acute Gastroenteritis in Children*, BMJ, 334.7583 (2007): 35-40. PMC. Web. 8 Feb. 2017.

<sup>7</sup> Ondansetron prescribing information

<sup>8</sup> Graves S. Nancy, *Acute Gastroenteritis*, Prim Care Clin Office Pract 40 (2013) 727-741 and company analysis.

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