



RedHill Biopharma Announces Two Oral Presentations on BEKINDA® 24 mg for acute gastroenteritis at the SAEM 2018 Annual Meeting

March 27, 2018

TEL-AVIV, Israel and RALEIGH, N.C., March 27, 2018 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal diseases and cancer, today announced that two abstracts¹ related to the successful Phase III study with BEKINDA® (RHB-102)² 24 mg for acute gastroenteritis and gastritis (the GUARD study) have been accepted for oral presentations at the Society for Academic Emergency Medicine (SAEM) 2018 Annual Meeting, May 16-17, 2018, at the JW Marriott Hotel in Indianapolis, IN.

The randomized, double-blind, placebo-controlled Phase III GUARD study with BEKINDA® 24 mg successfully met its primary endpoint of efficacy in the treatment of acute gastroenteritis and gastritis, and BEKINDA® 24 mg was found to be safe and well tolerated in this indication³. If approved for marketing by the FDA, BEKINDA® 24 mg could become the first 5-HT₃ antiemetic drug in the U.S. indicated for the treatment of acute gastroenteritis and gastritis.

The first presentation, entitled '*Treatment of Acute Gastroenteritis-Related Emesis with Bimodal Release Ondansetron (RHB-102)*', will be presented by Robert Silverman, MD, MS, Associate Professor of Emergency Medicine, Zucker School of Medicine at Hofstra/Northwell; Northwell Health, and Lead Investigator of the BEKINDA® Phase III GUARD study, on Wednesday, May 16, 2018, at 3:00 PM EDT. The abstract concludes that the Phase III GUARD study is the first study of acute gastroenteritis-related emesis showing benefit from any ondansetron preparation in adolescents and adults and suggests that acute gastroenteritis can be treated with a long-acting, bimodal release tablet, potentially avoiding the need for intravenous access.

The second presentation, entitled '*A 24 mg bimodal-release ondansetron pill (RHB-102) shows no evidence of QT interval prolongation*', will be presented by Joseph Miller, MD, MS, Associate Clinical Professor, Emergency Medicine, Henry Ford Hospital and Investigator of the BEKINDA® Phase III GUARD study, on Thursday, May 17, 2018, from 9:00 AM EDT. The abstract concludes that in patients with normal baseline corrected QT interval (QTc), 24 mg bimodal extended-release ondansetron caused no QTc prolongation in comparison to placebo.

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 and targets several gastrointestinal indications. A first Phase III clinical study with BEKINDA® 24 mg for the treatment of acute gastroenteritis and gastritis (the GUARD study) successfully met its primary endpoint. A Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) successfully met its primary endpoint.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases and cancer. RedHill commercializes and promotes three gastrointestinal products in the U.S.: **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg** - a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions; and **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104** with an ongoing first Phase III study for Crohn's disease and a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102)** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (iv) **YELIVA® (ABC294640)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **RHB-107 (formerly MESUPRON)**, a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. 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 promote Donnata[®] and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize 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 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; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other 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 22, 2018. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise, unless required by law.

Company contact:

Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

¹ The abstracts were authored by Stacey House, MD, PhD from Washington University in St. Louis; Joseph Miller, MD, MS from Henry Ford Hospital / Wayne State University; Luis Lovato, MD from Olive-View-UCLA Medical Center; Andrew Meltzer, MD, MS from George Washington University; Robert Silverman, MD, MS, Barry Hahn, MD and Jahn Avarello, MD from Northwell Health, and Ira Kalfus, MD, Reza Fathi, PhD, Gilead Raday, MSc and Terry Plasse, MD from RedHill Biopharma Ltd.

² BEKINDA[®] (RHB-102) is an investigational new drug, not available for commercial distribution.

³ Please click [here](#) for the full Phase III GUARD study results.

[Primary Logo](#)

Source: RedHill Biopharma Ltd.