



## RedHill Biopharma to Present Positive Phase II Results of BEKINDA® for IBS-D at Digestive Disease Week 2018

May 30, 2018

TEL-AVIV, Israel and RALEIGH, N.C., May 30, 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, today announced a presentation of Phase II results of BEKINDA® for diarrhea-predominant irritable bowel syndrome (IBS-D) at Digestive Disease Week® (DDW) 2018, being held June 2-5 in Washington, DC.

The poster<sup>1</sup> (abstract number: Su1188), entitled '*Randomized, double-blind, placebo-controlled, Phase 2 trial of ondansetron 12 mg bimodal release tablets for diarrhea-predominant irritable bowel syndrome (IBS-D)*', was selected as a poster of distinction and for highlighting in an oral presentation at DDW 2018.

Data from the poster will be presented by Dr. Terry F. Plasse, Medical Director at RedHill, as part of the IBS ePoster tour on Monday, June 4, 2018, at 12:00 PM EDT, at the DDW 2018 ePosters Theater. ePosters tours, curated by society experts, highlight the latest science featured in the Poster Hall in a small theater setting. The poster will also be presented for general viewing on Sunday, June 3, 2018, from 12:00 PM to 2:00 PM EDT in Hall C, at Walter E. Washington Convention Center, Washington, DC.

The abstract describes positive results of the Phase II study with BEKINDA® (RHB-102)<sup>2</sup> 12 mg for IBS-D. The Phase II study with BEKINDA® 12 mg successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). Results from the BEKINDA® Phase II study suggest that they compare favorably with previously reported efficacy outcome values from studies with Xifaxan® (rifaximin) and Viberzi® (eluxadoline) across all three efficacy endpoints<sup>3</sup>. RedHill plans to meet with the FDA in the third quarter of 2018 to discuss the design for possible pivotal Phase III studies with BEKINDA® 12 mg for IBS-D.

### 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. The path to potential approval of BEKINDA® for the intended indications of gastroenteritis and IBS-D is currently under discussion with the FDA.

### About Digestive Disease Week 2018:

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place June 2-5, 2018, at Walter E. Washington Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at [www.ddw.org](http://www.ddw.org).

### 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. 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; (iii) **RHB-204**, with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **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; (v) **YELIVA® (ABC294640)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) **RHB-106**, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **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](http://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 Donnatal<sup>®</sup> and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam<sup>®</sup>; (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.

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<sup>1</sup> The abstract was authored by Terry Plasse, MD, Danielle Abramson, PhD, Gilead Raday, MSc, Reza Fathi, PhD and Ira Kalfus, MD from RedHill Biopharma; Gary Barton, MD from Arkansas Gastroenterology; Evelyne Davidson, MD from New Phase Research & Development and Louis Velez, MD from Applied Research Center of Arkansas.

<sup>2</sup> BEKINDA<sup>®</sup> (RHB-102) is an investigational new drug, not available for commercial distribution.

<sup>3</sup> For more details, see RedHill's press releases dated October 3, 2017 and January 16, 2018. Xifaxan<sup>®</sup> (rifaximin) prescribing information: [www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022554lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022554lbl.pdf); Viberzi<sup>®</sup> (eluxadoline) prescribing information: [www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/206940s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206940s000lbl.pdf); Average absolute difference from reported Phase III studies; the theoretical comparison between the BEKINDA<sup>®</sup> 12 mg Phase II study results and reported data from studies of IBS-D-approved therapies serves as a general benchmark for the effect size observed with BEKINDA<sup>®</sup> 12 mg and should not be construed as a direct and/or equal comparison given that the studies were not identical in design, patient population and treatment period. For example, in the Xifaxan<sup>®</sup> 550 mg Phase III studies, the referenced efficacy endpoints were evaluated over a period of 4 weeks after 2 weeks drug administration, and in the Viberzi<sup>®</sup> 100 mg Phase III studies the referenced efficacy endpoints were evaluated after drug was administered and evaluated for 12 weeks. The studies were not conducted head-to-head in the same patient population.

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