



September 28, 2017

## RedHill Biopharma to Announce Top-Line Results from BEKINDA® 12 mg Phase II Study for IBS-D on October 3rd, 2017

TEL-AVIV, Israel and RALEIGH, N.C., Sept. 28, 2017 (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, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, expects to announce top-line results from the Phase II clinical study with BEKINDA® 12 mg (RHB-102)<sup>1</sup> for diarrhea-predominant irritable bowel syndrome (IBS-D) on Tuesday, October 3<sup>rd</sup>, 2017.

The Company plans to host a conference call and webcast on October 3<sup>rd</sup>, 2017 at 9:00 a.m. EDT to discuss the top-line results from the BEKINDA® Phase II study for IBS-D. Dial-in information and webcast access will be available on the Company's website on the day of the call: <http://ir.redhillbio.com/events.cfm>

BEKINDA® is a proprietary, bimodal extended-release, once-daily, oral pill formulation of the antiemetic drug ondansetron, targeting several gastrointestinal indications.

The randomized, double-blind, placebo-controlled Phase II study is evaluating the efficacy and safety of BEKINDA® 12 mg in adults, 18 years and older, who suffer from IBS-D. The study enrolled 127 subjects at 16 clinical sites in the U.S.

### 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. Positive top-line results from a Phase III clinical study with BEKINDA® 24 mg in the U.S. for acute gastroenteritis and gastritis (the GUARD study) were announced in June 2017. 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 patient treatment completed and top-line results expected to be announced on Tuesday, October 3<sup>rd</sup>, 2017.

### About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange: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 promotes three gastrointestinal products in the U.S. - **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, **EnteraGam®**, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools, and **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. RedHill's clinical-stage pipeline includes: (i) **TALICIA™ (RHB-105)** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study and an ongoing confirmatory 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 a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102)** - a once-daily oral pill formulation of ondansetron with successful top-line results from a 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® (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 protease inhibitor, targeting pancreatic cancer and other solid tumors and (vii) **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 two EU member states under the European Decentralized Procedure (DCP). 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 market Donnata<sup>®</sup> and 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 of 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; and (xii) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xiii) the Company's Expanded Access Program, which allows patients with life-threatening diseases potential access, subject to regulatory and other approvals, to RedHill's investigational new drugs that have not yet received regulatory marketing approval, if a patient suffers an adverse experience using such investigative drug, potentially adversely affecting the clinical development program of that investigational product or the Company generally; (xiv) competitive 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 23, 2017. 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.

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<sup>1</sup> BEKINDA<sup>®</sup> is an investigational new drug, not available for commercial distribution.

 [Primary Logo](#)

Source: RedHill Biopharma Ltd.

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