



## RedHill Biopharma Late-Breaking Abstract on Positive Phase III Crohn's Disease Study with RHB-104 to be Presented at UEG Week 2018

October 10, 2018

TEL-AVIV, Israel and RALEIGH, N.C., Oct. 10, 2018 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](#) (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal diseases, today announced that a late-breaking abstract on the positive Phase III study with RHB-104 in Crohn's disease (MAP US study) will be presented at the upcoming United European Gastroenterology Week (UEG Week 2018), October 20-24, 2018, in Vienna, Austria.

The presentation will highlight data from the MAP US Phase III study of RHB-104, including subgroup analysis of treatment with and without anti-TNF agents. Positive top-line results from the MAP US Phase III study were announced in July 2018. The study successfully met its primary endpoint and key secondary endpoints, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104.

"As additional data from the MAP US Phase III study becomes available, we continue to learn more about the efficacy and safety of orally-administered RHB-104 and its potential to address significant unmet medical needs in Crohn's disease," said **Ira Kalfus, MD, RedHill's Medical Director**. "We are excited to present this positive top-line data from the MAP US study at the upcoming UEG conference."

The late breaking abstract, entitled '*Phase III Randomized, Double Blind, Placebo-Controlled, Multicenter, Parallel Group Study To Assess The Efficacy And Safety Of Add-On Fixed-Dose Anti-Mycobacterial Therapy (RHB-104) In Moderately To Severely Active Crohn's Disease (MAP US)*' will be presented by Professor David Y. Graham, Lead Investigator of the MAP US study, on Monday, October 22, 2018, at 2-3 p.m., Room C (session: Clinical trials in IBD).

### About RHB-104:

RHB-104 is a proprietary, orally-administered antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties, with positive top-line results from a first Phase III study. RHB-104 was developed based on the hypothesis that Crohn's disease is caused by *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. The development of RHB-104 is consistent with the growing awareness of the possibility that a bacterially-induced dysregulated immune system may contribute to the pathogenesis of various autoimmune diseases of unknown etiology. Positive top-line results from the first Phase III study with RHB-104 in Crohn's disease (the MAP US study) were announced in July 2018. The study successfully met its primary endpoint and key secondary endpoints. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a population pharmacokinetic (pop-PK) study is ongoing as part of the Phase III MAP US study. Additionally, an open-label extension Phase III study (MAP US2 study) is ongoing to assess the safety and efficacy of RHB-104 in subjects who have completed week 26 assessments in the ongoing Phase III MAP US study and remain with active Crohn's disease (CDAI  $\geq$  150). Additional clinical studies are likely to be required to support a U.S. NDA for RHB-104.

### 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 four gastrointestinal products in the U.S.: **Donnatal**<sup>®</sup> - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi**<sup>®</sup> - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **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**<sup>®</sup> - 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**<sup>®</sup> (**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 positive top-line results from a 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**<sup>®</sup> (**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**<sup>®</sup> (**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.

*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>, Mytesi<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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Source: RedHill Biopharma Ltd.