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## **RedHill Biopharma Announces Expected Timeline for DSMB meeting and Provides Update on Enrollment in the RHB-104 Phase III Study for Crohn's Disease**

- ▮ **The second independent Data and Safety Monitoring Board (DSMB) meeting of the RHB-104 Phase III study for Crohn's disease (MAP US study) is planned to be held in late July 2017 and will assess the safety and efficacy of RHB-104 in the first 222 subjects who have completed week 26 assessments**
- ▮ **The DSMB meeting will include an interim efficacy analysis and an evaluation of an option for early stop for success for overwhelming efficacy; its recommendation is planned to be announced by early August 2017**
- ▮ **To date, approximately 300 patients of the planned total of 410 patients have been enrolled in the ongoing Phase III MAP US study**
- ▮ **The MAP US study is a randomized, double-blind, placebo-controlled Phase III study evaluating the safety and efficacy of RHB-104 in patients with moderately to severely active Crohn's disease, with a primary endpoint of remission at week 26**
- ▮ **An ongoing open-label extension Phase III study (MAP US2 study) is evaluating the safety and efficacy of RHB-104 in patients who have completed 26 weeks of treatment in the Phase III MAP US study and remain with active Crohn's disease; these patients have the opportunity to receive treatment with RHB-104 for a 52-week period in the Phase III open-label extension study**

TEL-AVIV, Israel and RALEIGH, N.C., July 12, 2017 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange: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 second independent Data and Safety Monitoring Board (DSMB) meeting of the RHB-104 Phase III study for Crohn's disease (the MAP US study) is expected to convene in late July 2017 and will assess the safety and efficacy of RHB-104 in the first 222 subjects who have completed week 26 assessments. RedHill expects to announce the recommendation of the DSMB meeting by early August 2017.

The independent DSMB meeting will conduct safety and interim efficacy analyses and will evaluate the option for an early stop for success for overwhelming efficacy, according to a pre-specified statistical significance threshold for overwhelming efficacy of RHB-104 versus placebo at the primary endpoint (two-sided p-value < 0.003). The primary endpoint of the MAP US study is disease remission, defined as a reduction in Crohn's Disease Activity Index (CDAI) to less than 150 at week 26. Assuming the study is not stopped for success or inefficacy following the DSMB meeting, completion of recruitment for the MAP US study is expected by the beginning of 2018.

Additionally, the Company updated that it has completed the enrollment of approximately 300 out of the 410 subjects planned to be enrolled in the RHB-104 Phase III study for Crohn's Disease (the MAP US study).

RHB-104 is a proprietary, orally-administered, potentially groundbreaking, antibiotic combination therapy with potent intracellular, antimycobacterial and anti-inflammatory properties, targeting a suspected underlying bacterial infectious cause of Crohn's disease, *Mycobacterium avium subspecies paratuberculosis* (MAP).

The MAP US study is a randomized, double-blind, placebo-controlled first Phase III study evaluating the safety and efficacy of RHB-104 in patients with moderately to severely active Crohn's disease (defined as CDAI between 220 and 450). The MAP US study is being conducted in up to 150 clinical sites in the U.S, Canada, Europe, Israel, Australia and New Zealand. Additional clinical data will need to be generated to support a U.S. New Drug Application (NDA) for RHB-104.

In December 2016, a first pre-planned independent DSMB meeting reviewed safety data from the ongoing MAP US study and provided a unanimous recommendation to continue the study as planned. Assuming the Phase III MAP US study is not stopped early, a third, safety-focused, independent DSMB meeting will be held once 75% of the 410 patients planned to be enrolled in the study will have completed 26 weeks of study participation.

RedHill recently initiated an open-label extension Phase III study (MAP US2 study) to the first Phase III MAP US study with RHB-104 for the treatment of Crohn's Disease. The MAP US2 study is intended to assess the safety and efficacy of RHB-104 in patients who have completed 26 weeks of treatment in the MAP US Phase III study and remain with active Crohn's disease (CDAI > 150) at week 26, the MAP US study's primary endpoint. These patients have the opportunity to receive treatment with RHB-104 for a 52-week period in the open-label MAP US2 extension study. The data collected in the MAP US2 study will be supplemental to the MAP US study data. The MAP US2 study's primary endpoint is disease remission at week 16, defined as CDAI of less than 150. The MAP US2 study is planned to enroll approximately 100 subjects in up to 150 clinical sites in the U.S., Canada, Europe, Israel, Australia and New Zealand. Additional open-label studies with RHB-104 for Crohn's disease are planned to provide further supportive clinical data for potential future marketing applications.

The clinical studies with RHB-104 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 RHB-104:**

Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study), RHB-104 is a proprietary, orally-administered, potentially groundbreaking oral antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is related to *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. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by Pharmacia/Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a long-term population pharmacokinetic (pop-PK) study is ongoing as part of the Phase III MAP US study. Additionally, an open-label extension Phase III study (the MAP US2 study) is ongoing to assess the safety and efficacy of RHB-104 in patients who have completed week 26 assessments in the ongoing Phase III MAP US study and remain with active Crohn's disease (CDAI > 150) at week 26. RHB-104 is covered by several issued and pending patents. RedHill also completed a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (the CEASE MS study), with top-line final results suggesting meaningful positive safety and clinical signals upon 24 weeks of treatment with RHB-104 as an add-on therapy, thereby supporting further clinical development. RHB-104 was granted Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA for the treatment of nontuberculous mycobacteria (NTM) infections, providing a Fast-Track development pathway, as well as NDA Priority Review and an additional five years of U.S. market exclusivity, if approved. RedHill is in discussions with the FDA regarding the development of RHB-104 development program for NTM infections.

#### **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 two gastrointestinal products in the U.S. - **Donnatal**<sup>®</sup>, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, and **EnteraGam**<sup>®</sup>, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's clinical-stage pipeline includes: (i) **TALICIA**<sup>™</sup> (**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 QIDP status for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA**<sup>®</sup> (**RHB-102**) - a once-daily oral pill formulation of ondansetron with successful top-line results in 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**<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 protease inhibitor, targeting pancreatic cancer 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 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 Donnatal<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) 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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