March 21, 2017

RedHill Biopharma Announces First Patient Dosed in the Open-Label Extension Study to the Phase III Study with RHB-104 for Crohn's Disease

- **A first randomized, double-blind, placebo-controlled Phase III clinical study with RHB-104 for the treatment of Crohn's disease (the MAP US study) is ongoing in the U.S. and additional countries**
- **The open-label extension study (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 ongoing MAP US Phase III study and remain with active Crohn's disease (CDAI > 150); these patients have the opportunity to receive treatment with RHB-104 for a 52-week period in the open-label extension study**
- **The MAP US2 open-label extension study is considered separate from the ongoing MAP US Phase III study and data collected will be supplemental to the MAP US study data**
- **A second independent DSMB meeting for the MAP US Phase III study is expected in mid-2017, including an interim efficacy analysis and an evaluation of an option for early stop for success for overwhelming efficacy**
- **RHB-104 is a proprietary, orally-administered, potentially groundbreaking antibiotic combination therapy with potent intracellular, antimycobacterial and anti-inflammatory properties**

TEL-AVIV, Israel, March 21, 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 dosing of the first patient in the open-label extension study to the Phase III study with RHB-104 for the treatment of 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.

The MAP US study is a randomized, double-blind, placebo-controlled first Phase III study, intended to evaluate the safety and efficacy of RHB-104 in patients with moderately to severely-active Crohn's disease (defined as Crohn's Disease Activity Index (CDAI) between 220 and 450). To date, 266 patients out of a planned total of 410 patients have been enrolled in the study, which is being conducted in up to 150 clinical sites in the U.S, Canada, Europe, Israel, Australia and New Zealand. A long-term population pharmacokinetic (pop-PK) study is also ongoing as part of the MAP US study. Additional studies will be required to support a U.S. New Drug Application (NDA) for RHB-104.

The open-label extension study (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 ongoing 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 extension study. This study is considered separate from the ongoing MAP US Phase III study, and data collected will be supplemental to the MAP US study data. The open-label extension study's primary endpoint is disease remission at week 16, defined as CDAI less than 150. The open-label extension 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 being planned by RedHill, to provide further supportive clinical data for potential future marketing applications.

A second independent Data and Safety Monitoring Board (DSMB) meeting of the MAP US Phase III study, expected in mid-2017, will include an interim efficacy analysis and will evaluate the option for an early stop for success for overwhelming efficacy, according to a pre-specified statistical significance threshold. Assuming the study is not stopped for success or inefficacy following the DSMB meeting in mid-2017, completion of recruitment for the MAP US study is expected by the end of 2017. 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.

The development of RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease, and potentially other autoimmune diseases, are 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.

The MAP US Phase III study is registered on 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 caused by *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. 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 study (the MAP US2 study) is ongoing to assess the safety and efficacy of RHB-104 in patients who have completed 26 weeks of treatment 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 has 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). Top-line final results from the CEASE MS study suggest meaningful positive safety and clinical signals upon 24 weeks of treatment with RHB-104 as an add-on therapy, thereby supporting further clinical development.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE: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 has a U.S. co-promotion agreement with Concordia for **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis. RedHill's clinical-stage pipeline includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first 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® (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing 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 Germany in October 2015. 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 market Donnatal®, (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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