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ASIA EDITION

RedHill Biopharma announces dosing of first patient in the phase III study with RHB-104 for Crohn's Disease

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RedHill Biopharma Ltd., 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, has 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.