December 13, 2016

RedHill Biopharma Announces Positive and Unanimous DSMB Recommendation for Continuation of Phase III Study with RHB-104 for Crohn's Disease

- **Following a pre-planned review of safety data, RedHill has received a unanimous recommendation from the independent Data and Safety Monitoring Board (DSMB) to continue the MAP US Phase III study with RHB-104 for Crohn's disease as planned, without any modifications**

- **A second DSMB meeting, expected in Q2/2017, will include an interim efficacy analysis and will evaluate the option of an early stop for success for overwhelming efficacy, according to a pre-specified statistical significance threshold**

TEL-AVIV, Israel, Dec. 13, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today reported that, following a pre-planned review of safety data from its ongoing Phase III study with RHB-104 for Crohn's disease (the MAP US study) by an independent Data and Safety Monitoring Board (DSMB), it has received a unanimous recommendation to continue the study as planned, without any modifications.

RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. 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 ongoing 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, 242 patients have been enrolled out of a planned total of 410 patients in up to 150 clinical sites in the U.S, Canada, Europe, Israel, Australia and New Zealand.

Subjects enrolled in the MAP US study are randomized 1:1 to receive RHB-104 or a placebo, with a primary endpoint of disease remission, defined as reduction in CDAI to less than 150 at week 26. Secondary and exploratory endpoints include, among others, state of response at week 26, maintenance of remission through week 52, endoscopic evaluation of mucosal healing and efficacy outcome measures in relation to the presence of MAP bacterial infection. Additional studies will be required to support a U.S. New Drug Application (NDA) for RHB-104.

Two additional independent DSMB meetings are expected to take place in the MAP US study after 50% and after 75% of the 410 patients planned to be enrolled in the study will complete 26 weeks of study participation. The second independent DSMB meeting is expected in the second quarter of 2017 after the first 205 patients are expected to complete 26 weeks of study participation (patient 205 was randomized in August 2016).

The second DSMB meeting will include safety and interim efficacy analysis and could potentially provide the opportunity to expedite the data locking process for the final analysis, once the study is complete. Importantly, this independent DSMB meeting will evaluate the option of an early stop for success for overwhelming efficacy, according to a pre-specified statistical significance threshold for analysis of RHB-104 versus placebo in the primary endpoint. If the pre-specified threshold is met at the second DSMB meeting, the study could be stopped for efficacy or inefficacy. If the pre-specified threshold is not met during the interim analysis, the MAP US study is planned to continue through randomization of all 410 patients and follow-up at week 26.

Taking into account the increase in the total number of patients planned in the MAP US study, and assuming the study is not stopped for success or inefficacy following the DSMB meeting in the second quarter of 2017, completion of recruitment is expected by the end of 2017.

RedHill is advancing its preparation to initiate an open-label extension study for all patients who have completed 26 weeks of treatment in the MAP US study and failed to achieve remission at week 26, the study's primary endpoint. Patients with a

Crohn's Disease Active Index (CDAI) score of greater than 150 at week 26 will be offered the opportunity to receive treatment with active drug (RHB-104) for a 52-week period. This study is considered separate from the MAP US study and data collected will be supplemental to the MAP US study data.

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 and potentially groundbreaking oral antibiotic combination therapy, with potent intracellular, anti-mycobacterial 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. 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 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 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's pipeline of proprietary products 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 and a completed proof-of-concept Phase IIa study for multiple sclerosis; (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 uPA inhibitor, targeting gastrointestinal 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.

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 establish and maintain corporate collaborations; (vi) 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; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. 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 25, 2016. 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.

Company contact:

Adi Frish

Senior VP Business Development &

Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

IR contact (U.S.):

Marcy Nanus

Senior Vice President

The Trout Group

+1-646-378-2927

Mnanus@troutgroup.com

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