RedHill Biopharma Announces Full Results from Positive MAP US Phase 3 Study and Supportive Top-Line Results from MAP US2 Open-Label Extension Study with RHB-104 in Crohn's Disease

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TEL-AVIV, Israel and RALEIGH, N.C., Oct. 11, 2019 (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 clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases, today announced full Week 52 results for all subjects in the previously announced positive Phase 3 randomized, controlled study of RHB-104 in Crohn's disease (the "MAP US study") and supportive top-line results from the open-label extension Phase 3 study (the "MAP US2 study").

The full Week 52 results of blinded treatment in the MAP US Phase 3 study with RHB-104 were consistent with the previously reported positive outcomes of the study. The study continued to meet its primary endpoint of clinical remission (CDAI < 150) at week 26 (36.7% vs. 22.4%, p=0.0048), key secondary endpoints of maintenance of remission at weeks 16 and 52 (25.9% vs. 12.1%, p=0.0016) and, notably, durable clinical remission on all visits, week 16 through 52 (18.7% vs. 8.5%, p=0.0077, RHB-104 vs. placebo, respectively).

In the analysis of the complete safety information for the study, a top-line electrocardiogram (ECG) monitoring report for the MAP US study recently received and shared with FDA, demonstrated evidence of progressive prolongation of the QTcF interval across visits, with the largest placebo-corrected ΔQTcF (ΔΔQTcF) of 30.6 ms at Week 52 of treatment with RHB-104. None of these QT abnormalities resulted in adverse cardiac events. Clofazimine, as well as clarithromycin (another active component of RHB-104), are known to be associated with QT prolongation. RedHill continues to analyze the data from the RHB-104 studies, including QT prolongation findings and various pharmacokinetic and pharmacodynamic models and, as previously announced, intends to meet with the FDA again in the coming months to discuss the RHB-104 program, including these data.

The MAP US2 open-label extension Phase 3 study evaluated the safety and efficacy of RHB-104 in subjects from the MAP US study with persistent active Crohn's disease (Crohn's Disease Active Index (CDAI) ≥ 150) after 26 weeks of blinded study therapy. A total of 54 subjects entered the open-label extension study and 30 subjects completed 52 weeks of treatment.

Interim top-line results from the MAP US2 study demonstrated 27.8% clinical remission with RHB-104 at week 16 and 22.2% remission at week 52[1]. Of the MAP US2 subjects who were previously randomized to the placebo arm (as an add-on to standard-of-care therapies) in the MAP US study and treated with RHB-104 for the first time in the MAP US2 study, 31.6% achieved remission at week 16 and 26.3% achieved remission at week 52. These results further support the potential clinical benefit of treatment with RHB-104 in Crohn's disease patients.

RHB-104 was found to be generally safe and well tolerated. The incidence of treatment emergent adverse events, serious adverse events and reported adverse events leading to discontinuation in the MAP US2 study were lower than in the active arm of the MAP US study (77.8% vs. 87.3%, 7.4% vs. 18.7% and 9.3% vs. 21.1%, respectively). Similar trends were observed in MAP US2 subjects who received concomitant anti-TNFs, consistent with the safety of treatment with RHB-104 in combination with anti-TNF agents.

The top-line results and subsequent analyses were provided to RedHill by an independent third party following an independent analysis and remain subject to completion of the independent review and analysis of the underlying data, including all safety, secondary and other outcome measures, and completion of the Clinical Study Report (CSR).

The clinical studies with RHB-104 are registered on www.clinicaltrials.gov, a web-based service of the U.S. National Institute of Health, that provides access to information on publicly and privately-supported clinical studies.

About RHB-104:
RHB-104 is a proprietary, orally administered antibiotic combination therapy, with intracellular, antimycobacterial and anti-inflammatory properties. The randomized, double-blind, placebo-controlled, first Phase 3 study with RHB-104 in Crohn's disease (the MAP US study) successfully met both its primary endpoint and key secondary endpoints and presented the benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease, including anti-TNF agents. The Company also reported supportive top-line results from an open-label extension Phase 3 study (MAP US2) evaluating the safety and efficacy of RHB-104 in subjects with persistent active Crohn's disease after 26 weeks of blinded study therapy in MAP US. 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.

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 clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.: **Donnatal® -** a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam® -** a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi® -** an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. RedHill's key clinical late-stage development programs include: (i) **RHB-105 (Talicia®)** for the treatment and eradication of *Helicobacter pylori* infection with a U.S. NDA submitted and accepted for priority review with a target PDUFA action date of November 2, 2019; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous

mycobacteria (NTM) infections; (iv) **RHB-102** (**Bekinda®**), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (v) **Yeliva® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. 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 the Company's continuing review and quality control analysis of clinical data, 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 related to the occurrence or timing of the RHB-105 (Talicia®) PDUFA action date, risks related to the commencement or timing of our clinical trials with RHB-104, RHB-204, RHB-102 (Bekinda®) and Yeliva®, risks related to meetings scheduled with the FDA, including with regard to RHB-104 for Crohn's disease, risks relating to side effects associated with use of our therapeutic products, as well as 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, and the timing of the commercial launch of its therapeutic candidates; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (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 commercialize and promote Donnatal ®, EnteraGam® and Mytesi®; (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; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. 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 26, 2019, as amended on May 15, 2019. 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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[1] Results were provided by independent third party prior to database lock and are not final

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