RedHill Biopharma Receives Allowance for New U.S. Patent Covering RHB-104 for Crohn's Disease and RHB-204 for NTM Infections

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- **The new patent expands the robust patent portfolio covering RHB-104 and RHB-204**
- **RedHill plans to initiate a pivotal Phase 3 study with RHB-204 for the treatment of pulmonary nontuberculous mycobacteria (NTM) infections in the second half of 2019**
- **RedHill plans to meet with the FDA in the second half of 2019 to discuss the design of a confirmatory Phase 3 with RHB-104 for Crohn's disease**

TEL-AVIV, Israel and RALEIGH, N.C., June 10, 2019 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on gastrointestinal diseases, today announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a new patent covering RHB-104 for Crohn's disease and RHB-204 for *Mycobacterium avium complex* (MAC) disease, the most common cause of pulmonary nontuberculous mycobacteria (NTM) infections[1]. Once granted, the patent is expected to be valid until at least 2029.

Danielle Abramson, Ph.D., RedHill's Vice President of Intellectual Property and Research, stated: "We continue to build and strengthen our intellectual property portfolio covering both RHB-104 and RHB-204. Once this new patent is granted, the robust patent portfolio for RHB-104 will include seven issued U.S. patents, three of which also protect RHB-204, as well as additional issued and pending patents worldwide. We continue to work diligently to expand the existing patent portfolio covering our advanced clinical programs including Talicia for *H. pylori* infection for which a new drug application (NDA) has been submitted earlier this quarter with priority review eligibility."

RedHill plans to initiate a pivotal Phase 3 study with RHB-204 for the treatment of pulmonary NTM infections in the second half of 2019, subject to completion of the ongoing supportive non-clinical program and additional input from the U.S. Food and Drug Administration (FDA). The study is intended to assess the efficacy and safety of RHB-204 and potentially support its approval as a stand-alone, first-line treatment for pulmonary NTM infections caused by MAC.

RedHill plans to meet with the FDA in the second half of 2019 to discuss the development path toward potential approval of RHB-104, including the design of a confirmatory Phase 3 study. The MAP US randomized, double-blind, placebo-controlled first Phase 3 study with RHB-104 for Crohn's disease successfully met both its primary endpoint and its key secondary endpoints and presented the broad benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease, including anti-TNFs.

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 anti-retroviral therapy. RedHill's key clinical late-stage development programs include: (i) **Talicia® (RHB-105)** for the treatment of *Helicobacter pylori* infection with a U.S. NDA submitted; (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) **BEKINDA® (RHB-102),** 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.

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, the grant of patents by regulatory authorities, the initiation of a pivotal Phase 3 study with RHB-204 and the timing of FDA meetings, 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; (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®, Mytesi® and

Esomeprazole Strontium Delayed-Release Capsules 49.3 mg; (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 SECon February 26, 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] Wassilew, Nasstasja, et al. "Pulmonary disease caused by non-tuberculous mycobacteria." Respiration 91.5 (2016): 386-402.

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