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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- **Once granted, the new patent, which covers both RHB-104 and RHB-204, is expected to be valid until at least 2029**
- **RedHill recently announced positive top-line results from the randomized, double-blind, placebo-controlled MAP US Phase III study with orally-administered RHB-104 in Crohn's disease**
- **The MAP US Phase III study met its primary endpoint as well as key secondary endpoints; 331 subjects received RHB-104 or placebo, on top of baseline background standard-of-care medications**
- **A pivotal Phase III study with RHB-204 for pulmonary NTM infections is planned to be initiated in Q1/2019**

TEL-AVIV, Israel and RALEIGH, N.C., Aug. 13, 2018 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal diseases, today announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a new formulation patent, expected to be valid until at least 2029, that further expands the Company's intellectual property portfolio covering RHB-104 for Crohn's disease and RHB-204 for pulmonary nontuberculous mycobacteria (NTM) infections.

Danielle Abramson, Ph.D., RedHill's Vice President, Intellectual Property & Research, said: "RedHill has a robust patent portfolio covering the proprietary formulation of RHB-104 and its use in treating Crohn's disease, including several issued U.S. patents. We are particularly pleased with the timing of this new patent as it is coming on the heels of the positive top-line results from the first Phase III study with RHB-104 in Crohn's disease and ahead of the planned initiation of a pivotal Phase III study with RHB-204 for pulmonary nontuberculous mycobacteria infections."

The MAP US Phase III study is registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institute of Health, which provides access to information on publicly and privately-supported clinical studies.

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 late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes four gastrointestinal products in the U.S.: **Donnatal®-** a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi®** - an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg -** a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions, and **EnteraGam®-** a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104,** with positive top-line results from a first Phase III study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102),** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II 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 IIa study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107 (formerly MESUPRON),** a Phase II-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, risks relating to the completion of the independent review and analysis of the underlying data relating to the top-line results from the first Phase III study with RHB-104 in Crohn's disease, including all safety, secondary and other outcome measures, and completion of the Clinical Study Report (CSR) and 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 promote Donnatal ®, Mytesi® andEsomeprazole Strontium Delayed-Release Capsules 49.3 mgand commercialize EnteraGam®; (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; and (xiv) competition from other 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 SECon February 22, 2018. 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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