



RedHill Biopharma Receives Allowance for New U.S. Patent Covering RHB-106, an Encapsulated Bowel Preparation

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- **Once granted, the new formulation patent is expected to be valid until at least 2033**
- **RHB-106 is an encapsulated bowel preparation with worldwide rights licensed to Salix Pharmaceuticals**
- **RedHill and Salix recently amended their license agreement to include certain development activities, timelines and milestones to be achieved, as well as collaboration in relation to intellectual property rights**

TEL-AVIV, Israel and RALEIGH, N.C., Aug. 20, 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 covering RHB-106, which is expected to be valid until at least 2033. Additional patent applications for RHB-106 are pending in numerous other countries.

RHB-106 is an encapsulated bowel cleanser licensed to Salix Pharmaceuticals ("Salix"), a wholly-owned subsidiary of Bausch Health Companies Inc. (NYSE: BHC and TSX: BHC).

RedHill recently amended its 2014 worldwide license agreement with Salix relating to RHB-106, as well as additional related rights. The amendment clarified Salix's future development efforts and provides for enhanced involvement by RedHill in certain intellectual property matters and increased the lower end of the range of royalty payments to be paid to RedHill on net sales from low single digits to high single digits. Milestone payments remain unchanged. RedHill continues to assist Salix in the development of RHB-106, as needed.

About RHB-106:

RHB-106 is an encapsulated formulation intended for the preparation and cleansing of the gastrointestinal tract prior to abdominal procedures and diagnostic tests, such as colonoscopies, barium enemas or virtual colonoscopies, as well as surgical interventions, such as laparotomies. RHB-106 is a tasteless solid oral dosage, potentially allowing for an unobstructed procedure with reduced side effects and improved patient compliance.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on 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 drug 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 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® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and 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 SEC on 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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