



## RedHill Biopharma Announces Acceptance of Oral Presentations on RHB-105 (*H. pylori*) and RHB-104 (Crohn's Disease) Phase 3 Data at ACG 2019 Annual Scientific Meeting

August 21, 2019

TEL-AVIV, Israel and RALEIGH, N.C., Aug. 21, 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 that it will present data from the positive Phase 3 clinical studies of RHB-105 (Talcia<sup>®</sup>)<sup>1</sup> for *H. pylori* infection and RHB-104 for Crohn's disease at the upcoming American College of Gastroenterology (ACG) 2019 Annual Scientific Meeting (October 25-30, 2019). In addition, an oral presentation on RHB-105 (Talcia) was also accepted for presentation at the XXXII<sup>nd</sup> International Workshop on Helicobacter & Microbiota in Inflammation and Cancer of the European Helicobacter and Microbiota Study Group (EHMSG 2019) (September 5-7, 2019).

### 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<sup>®</sup>**- a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam<sup>®</sup>**- a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi<sup>®</sup>**- 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 (Talcia<sup>®</sup>)** 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) **Bekinda<sup>®</sup> (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<sup>®</sup> (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](http://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 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 approval of the NDA for RHB-105 (Talcia<sup>®</sup>) by the FDA and such approval's timing, the initiation and timing of the commercial launch of RHB-105 (Talcia<sup>®</sup>), the timing of meetings scheduled with the FDA, including in regards with RHB-104 for Crohn's disease, 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<sup>®</sup>, EnteraGam<sup>®</sup> and Mytesi<sup>®</sup>; (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.*

<sup>1</sup> RHB-105 (Talcia<sup>®</sup>) and RHB-104 are investigational new drugs, not available for commercial distribution. RHB-105 (Talcia<sup>®</sup>) is a proposed tradename and is subject to Food and Drug Administration review and approval of the RHB-105 (Talcia<sup>®</sup>) NDA.

Company contact:

Adi FrishSenior VP Business Development & Licensing  
RedHill Biopharma  
+972-54-6543-112  
[adi@redhillbio.com](mailto:adi@redhillbio.com)

IR contact (U.S.):  
Timothy McCarthy, CFA, MBA  
Managing Director, Relationship Manager  
LifeSci Advisors, LLC  
+1-212-915-2564  
[tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)



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