



RedHill Biopharma Initiates Co-Promotion of HIV/AIDS Anti-Diarrheal Drug Mytesi®

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- **Mytesi® is an FDA-approved anti-diarrheal prescription drug indicated for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy (ART)**
- **Mytesi® is the fourth product being promoted by RedHill's gastrointestinal-focused U.S. sales force, setting the stage for potential U.S. launch of RedHill's late clinical-stage products, including TALICIA® (RHB-105) for *H. pylori* infection, with confirmatory Phase III study top-line results expected in Q4/2018**

TEL-AVIV, Israel and RALEIGH, N.C., July 25, 2018 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](#) (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal (GI) diseases, today announced that it has initiated promotion of Mytesi® (crofelemer 125 mg delayed-release tablets)¹, a first-in-class anti-secretory prescription drug product of Napo Pharmaceuticals (Napo), a wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar), that is approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. RedHill's co-promotion efforts will target gastroenterologists and select primary care physicians in the U.S., complementing the efforts of Napo's direct sales force, which has been fully deployed since the second quarter of 2018.

Mytesi® is the only drug that has been specifically studied in and FDA-approved for use in managing non-infectious diarrhea in people living with HIV/AIDS. The ADVENT study was a long-term Phase III, multicenter, randomized, placebo-controlled trial that enrolled 274 patients treated with either Mytesi® 125 mg bid or placebo. The results from ADVENT, which have previously been reported by Napo and Jaguar, show that by week 20 89% (n=162) of participating patients experienced a decrease in watery stools, with 83% having at least a 50% decrease; 72% at least a 75% decrease, and 56% a 100% decrease.

RedHill's U.S. commercial operations, headquartered in Raleigh, NC, include a gastrointestinal-focused sales force of approximately 40 sales representatives commercializing and promoting four GI-specialty products, Donnata® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)², EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI)³, Esomeprazole Strontium DR Capsules 49.3 mg and Mytesi® (crofelemer 125 mg delayed-release tablets)⁴ in select U.S. territories. RedHill's U.S. commercial operations are setting the stage for the potential U.S. launch of RedHill's late clinical-stage products, including TALICIA® (RHB-105)⁵ for *H. pylori* infection, with confirmatory Phase III study top-line results expected in the fourth quarter of 2018.

RedHill recently announced that it has entered into a co-promotion agreement with Napo, a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, granting RedHill the exclusive right to co-promote Mytesi® to certain gastroenterologists and primary care physicians. Napo's direct sales force, consisting of 18 highly experienced Mytesi® sales representatives, a national sales director, a regional business director, and a telesales representative, is focused on targeting primary care and infectious disease physicians who are high-volume ART prescribers (HIV specialists).

About Mytesi®:

Mytesi® (crofelemer) is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy (ART). Mytesi® is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi®. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at [Mytesi.com](#). Crofelemer, the active ingredient in Mytesi®, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

To submit adverse event reports or product complaint reports, contact Napo Pharmaceuticals, Inc. at at_napopharma@missionpharmacal.com or (844) 722-8256. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit <https://www.fda.gov/Safety/MedWatch/default.htm> or call 1-800-FDA-1088 (1-800-332-1088).

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.: **Donnata®** - 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 an ongoing 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, the risk that Co-Promotion Agreement with Napo Pharmaceuticals will not be extended, the risk that the top-line results of the Phase III study with TALICIA[®] for *H. pylori* will be later than expected, 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[®] 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.*

¹ Mytesi[®] (crofelemer 125 mg delayed-release tablets) is a first-in-class anti-secretory prescription drug approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. For more information, please see the prescribing information: http://mytesi.com/assets/mytesi_package_insert_june_2016.pdf.

² Donnatal[®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. For more information, please see the prescribing information: <http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-Information-DTC-REV-SE.pdf>.

³ EnteraGam[®] (serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

⁴ Mytesi[®] (crofelemer 125 mg delayed-release tablets) is a first-in-class anti-secretory prescription drug approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. For more information, please see the prescribing information: http://mytesi.com/assets/mytesi_package_insert_june_2016.pdf.

⁵ TALICIA[®] (RHB-102) is an investigational new drug, not available for commercial distribution.

Company contact:

Adi FrishSenior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
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

 Primary Logo

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