



RedHill Biopharma to Focus Commercial Efforts on Talicia® and Aemcolo®; Discontinuing Promotion of Legacy Products

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TEL-AVIV, Israel and RALEIGH, N.C., Jan. 21, 2020 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](#) (Nasdaq: [RDHL](#)) (Tel-Aviv Stock Exchange: [RDHL](#)) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases, today announced its decision to discontinue its co-promotion and commercialization agreements for Donnata® and EnteraGam® to enable a greater focus on its lead commercial products, Talicia®¹ and Aemcolo®², and create capacity for additional products.

RedHill provided a notice of termination to Entera Health regarding the license agreement for EnteraGam® and the co-promotion agreement with Advanz Pharma Corp. for Donnata® will not be renewed. RedHill has been promoting Donnata® and EnteraGam® since mid-2017.

"Prioritizing our commercial efforts allows us to focus on our most valuable products, Talicia® and Aemcolo®, as well as giving us capacity to bring on other important products, which are currently under discussion," said **Dror Ben-Asher, RedHill's Chief Executive Officer**. "Over the past 2.5 years, we've established a full U.S. commercial operation including a seasoned sales force, and built relationships with thousands of gastroenterologists, primary care and other healthcare providers across the country ahead of the planned Talicia® launch later this quarter. We would like to thank our partners at Advanz Pharma and Entera Health for the fruitful partnerships."

RedHill initiated promotion of Aemcolo® in the U.S. in December 2019. Talicia® was approved by the U.S. FDA in November 2019 and is planned to be launched in the first quarter of 2020.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: [RDHL](#)) (Tel-Aviv Stock Exchange: [RDHL](#)) is a specialty biopharmaceutical company, primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases. RedHill promotes the gastrointestinal drugs **Aemcolo®** and **Mytesi®** in the U.S. and is planning to launch **Talicia®** in the U.S. for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults³. RedHill's key clinical late-stage development programs include: (i) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102 (Bekinda®)**, with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **ABC294640 (Yeliva®)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation, and (vi) **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.

About Talicia® (omeprazole magnesium, amoxicillin and rifabutin)

INDICATION AND USAGE

Talicia is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of *Helicobacter pylori* infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Talicia and other antibacterial drugs, Talicia should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

Talicia contains omeprazole, a proton pump inhibitor (PPI), amoxicillin a penicillin-class antibacterial and rifabutin, a rifamycin antibacterial. It is contraindicated in patients with known hypersensitivity to any of these medications, any other components of the formulation, any other beta-lactams or any other rifamycin.

Talicia is contraindicated in patients receiving rilpivirine-containing products.

Talicia is contraindicated in patients receiving delavirdine or voriconazole.

Serious and occasionally fatal hypersensitivity reactions have been reported with omeprazole, amoxicillin and rifabutin.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.

Talicia may cause fetal harm. Talicia is not recommended for use in pregnancy.

Talicia may reduce the efficacy of hormonal contraceptives. An additional non-hormonal method of contraception is recommended when taking Talicia.

Talicia should not be used in patients with hepatic impairment or severe renal impairment.

Acute Interstitial Nephritis has been observed in patients taking PPIs and penicillins.

Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs. These events have occurred as both new onset and exacerbation of existing autoimmune disease.

The most common adverse reactions ($\geq 1\%$) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

To report SUSPECTED ADVERSE REACTIONS, contact RedHill Biopharma INC. at 1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full prescribing information for Talicia[®] is available at <http://bit.ly/2CozHNN>.

About Aemcolo[®] (rifamycin)

INDICATION AND USAGE

Aemcolo[®] (rifamycin) is an orally-administered, delayed-release, non-systemic antibiotic approved for the treatment of travelers' diarrhea caused by non-invasive strains of *Escherichia coli* (*E. coli*) in adults. Aemcolo[®] is the first antibiotic engineered with Cosmo Pharmaceuticals' Multi Matrix Technology (MMX[®]). MMX technology is designed to deliver the active pharmaceutical ingredients in a delayed and controlled manner directly to the lower intestine.

IMPORTANT SAFETY INFORMATION

Aemcolo is contraindicated in patients with a known hypersensitivity to rifamycin, any of the other rifamycin class antimicrobial agents, or any of the components in Aemcolo.

Aemcolo is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults. It is not recommended for use in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of *E. coli*.

The most common adverse reactions (incidence $>2\%$) are headache and constipation.

Clostridium difficile-Associated Diarrhea has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs after therapy or does not improve or worsens during therapy.

Aemcolo should be swallowed whole. Do not crush, break or chew the tablets. Do not take Aemcolo concomitantly with alcohol.

Risk of Persistent or Worsening Diarrhea Complicated by Fever and/or Bloody Stool: Aemcolo was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool or diarrhea due to pathogens other than noninvasive strains of *E. coli* and is not recommended for use in such patients. Discontinue use if diarrhea gets worse or persists more than 48 hours and consider alternative antibacterial therapy.

Full prescribing information for Aemcolo[®] is available at www.aemcolo.com.

To submit adverse event reports or product complaint reports, contact RedHill Biopharma, Inc. at 1(833)-ADR-HILL. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088).

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 related to the timing for the launch of Talicia[®] 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 and its FDA-approved products; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (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 and Talicia[®]; (v) the Company's ability to successfully commercialize and promote Talicia[®], Aemcolo[®], and Mytesi[®]; (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 investigational 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.

¹ Talicia[®] (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: <http://bit.ly/2CozHNN>.

² Aemcolo® (rifamycin) is indicated for the treatment of travelers' diarrhea caused by non-invasive strains of *Escherichia coli* (*E.coli*) in adults. For full prescribing information see: www.Aemcolo.com.

³ For full prescribing information see: Aemcolo®: www.Aemcolo.com; Mytesi®: www.Mytesi.com

Talicia®: <http://bit.ly/2CozHNN>.

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