NEWS RELEASE

RedHill's Aemcolo® Granted FDA QIDP 5-Year Exclusivity Extension

12/5/2022

Aemcolo granted five years' exclusivity under the FDA's Qualified Infectious Disease Product (QIDP) designation in addition to the five years NCE data exclusivity, extending regulatory exclusivity through to 2028

Aemcolo (rifamycin) is a non-systemic antibiotic whose delivery is targeted to the site of non-invasive Escherichia coli (E. coli) infection in the distal small bowel and colon, approved by the FDA for the treatment of Travelers' Diarrhea caused by non-invasive strains of E. coli in adults

Aemcolo is listed as an acute diarrhea antibiotic treatment recommendation in the Centers for Disease Control and Prevention (CDC) Yellow Book[1]

TEL AVIV, Israel and RALEIGH, N.C., Dec. 5, 2022 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that the U.S. Food and Drug Administration's (FDA) Exclusivity Board has granted Aemcolo®[2] five years' exclusivity under the Generating Antibiotic Incentives Now (GAIN) Act Qualified Infectious Disease Product (QIDP) designation, in addition to the five years' data exclusivity granted as a new chemical entity (NCE) for the treatment of travelers' diarrhea (TD) caused by non-invasive strains of Escherichia coli (E. coli) in adults.

Patricia Anderson, RedHill's Senior Vice President of Regulatory Affairs said: "Given the great concerns around maintaining effective therapeutic options for infectious diseases in the face of growing microbial resistance,

Aemcolo represents an important innovation to meet significant unmet need. This FDA grant of five additional years' exclusivity for Aemcolo under the FDA's Generating Antibiotic Incentives Now (GAIN) Act Qualified Infectious Disease Product (QIDP) designation, in addition to the five years awarded to Aemcolo based on new chemical entity exclusivity, will protect that innovation through to 2028."

Aemcolo, containing 194 mg of rifamycin as delayed-release tablets, is an orally-administered, non-systemic antibiotic employing MMX® technology, a proprietary drug delivery system that distributes rifamycin in a controlled manner to the lower intestine. Due to its non-systemic delivery, Aemcolo is associated with limited side effects and minimal potential for interactions with other medications.

Aemcolo is listed as an acute diarrhea antibiotic treatment recommendation in the Centers for Disease Control and Prevention (CDC) Yellow Book[1].

About Traveler's Diarrhea

Travelers' Diarrhea (TD) is the most common travel-related illness, affecting an estimated 10% to 40% of travelers annually[2]. Each year, approximately 70 million Americans travel abroad[3]. Attack rates of TD range up to 70% of travelers, depending on the destination and season of travel[4]. TD may often result in short-term morbidity adversely impacting travel plans. Untreated diarrhea can also lead to an underappreciated risk of chronic complications, including functional bowel disorders[5].

About Aemcolo (rifamycin)

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. Due to its non-systemic delivery, Aemcolo is associated with limited side effects and minimal potential for interactions with other medications.

Aemcolo is listed as an acute diarrhea antibiotic treatment recommendation in the Centers for Disease Control and Prevention (CDC) Yellow Book. The recommended dosage of Aemcolo is 388 mg (two tablets) orally, twice daily for three days.

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

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.

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.

You can report any side effects to RedHill Biopharma Inc. at 1-833-ADR-HILL or by contacting the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see **Complete Prescribing Information**.

INDICATION

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.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs, **Movantik®** for opioid-induced constipation in adults[6], **Talicia®** for the treatment of Helicobacter pylori (H. pylori) infection in adults[7], and **Aemcolo®** for the treatment of travelers' diarrhea in adults[2]. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (ABC294640)**, a first-in-class oral broad-acting, host-directed, SK2 selective inhibitor targeting multiple indications, including for pandemic preparedness, with a Phase 2/3 program for hospitalized COVID-19 and a Phase 2 program in oncology and a radiation protection program ongoing; (iii) **RHB-107** (**upamostat**), an oral broad-acting, host-directed serine protease inhibitor with potential for pandemic preparedness and is in Phase 3-stage development

as treatment for non-hospitalized symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; and (v) **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. More information about the Company is available at **www.redhillbio.com**/ **twitter.com/RedHillBio**.

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 the Company will not successfully commercialize its products; as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number and type 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®, and Aemcolo® and Movantik® ; (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, pre-clinical 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 March 18, 2021. 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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[1] **https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/travelers-diarrhea**

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

[3] Cosmo Pharmaceuticals Investor Presentation July 2019

[4] CDC Yellow Book

[5] Steffen R, et al. JAMA. 2015;313(1):71-80.

[6] Movantik® (naloxegol) is indicated for opioid-induced constipation (OIC). Full prescribing information see: **www.movantik.com**.

[7] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of H. pylori infection in adults. For full prescribing information see: **www.Talicia.com**.

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