Press Release

RedHill Biopharma Initiates U.S. Promotion of Aemcolo® for Travelers' Diarrhea

- **Aemcolo® (rifamycin) is a non-systemic antibiotic delivered directly to the site of non-invasive *E. coli* infection in the lower intestine**
- **Aemcolo® is approved by the FDA for the treatment of travelers' diarrhea, and is covered by a robust U.S. patent portfolio which, together with the U.S. marketing exclusivity, provides exclusivity until the end of 2028**
- **Approximately 70 million Americans travel abroad annually; Travelers' diarrhea may affect up to 70% of travelers depending on destination and season of travel**

TEL-AVIV, Israel and RALEIGH, N.C., December 17, 2019 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 that it has initiated promotion of Aemcolo® (rifamycin) in the U.S. for the treatment of travelers' diarrhea caused by non-invasive strains of *Escherichia Coli* (*E. coli)* in adults[1].

Aemcolo®, containing 194 mg of rifamycin as delayed-release tablets, is an orally-administered, non-systemic antibiotic employing MMX® technology, a proven and proprietary drug delivery system that distributes rifamycin in a controlled manner to the lower intestine. The recommended dosage of Aemcolo® is 388 mg (two tablets) orally, twice daily for three days.

[1] See full prescribing information: www.aemcolo.com

"We are excited to leverage our U.S. sales and marketing teams to educate patients and health care providers about Aemcolo® as an effective treatment for travelers' diarrhea. With the launch of Aemcolo® and ahead of the planned launch of Talicia® for the treatment of *H. pylori* infection in adults[2], we are actively expanding our sales force to approximately 140 reps, to deliver an optimal U.S. launch for both products," **said Rick D. Scruggs, Chief Operating Officer, U.S. Operations at RedHill.** "Every year, millions of Americans travel to countries where they are at high risk of infection with travelers' diarrhea. These travelers can avoid the risk of ruining several days of an expensive vacation, at the cost of potentially thousands of dollars, due to travelers' diarrhea if they plan ahead. Aemcolo® offers these travelers a non-systemic antibiotic with a targeted delivery system to fight the infection at its source and is recommended by the Centers for Disease Control and Prevention (CDC) Yellow Book. Travelers are also able to purchase prescription Aemcolo® online through the www.AemcoloForTravel.com website."

On October 18, 2019, RedHill announced that it had entered into a strategic collaboration with Cosmo Pharmaceuticals N.V. (SIX: COPN), including an exclusive license agreement for the U.S. rights to Aemcolo® and a simultaneous private investment by Cosmo Pharmaceuticals of $36.3 million in RedHill.

About Traveler's Diarrhea

Travelers' diarrhea (TD) is the most common travel-related illness, affecting an estimated 10% to 40% of travelers Annually[3]. Each year, approximately 70 million Americans travel abroad[4]. Attack rates of TD range up to 70% of travelers, depending on the destination and season of travel[5]. 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[6].

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.

INDICATION AND IMPORTANT SAFETY INFORMATION

Aemcolo® is indicated for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* (*E. coli*) in adults.

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[2] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213004lbl.pdf

[3] FDA. https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treat-travelers-diarrhea

[4] Cosmo Pharmaceuticals Investor Presentation July 2019

[5] CDC Yellow Book

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

Limitations of Use

Aemcolo® is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of *E. coli*.

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

CONTRAINDICATION

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®.

WARNINGS AND PRECAUTIONS

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 caused by pathogens other than *E. coli* and is not recommended for use in such patients.

Discontinue Aemcolo® if diarrhea gets worse or persists more than 48 hours and consider alternative antibacterial therapy.

Clostridium difficile-Associated Diarrhea (CDAD)

CDAD has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

Consider CDAD in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Development of Drug-Resistant Bacteria

Prescribing Aemcolo® in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

Discontinuation of Aemcolo® due to adverse reactions occurred in 1% of patients. The most frequent adverse reactions were abdominal pain (0.5%) and pyrexia (0.3%).

Adverse reactions that occurred in at least 2% of Aemcolo®-treated patients and with a higher incidence than in the placebo or ciprofloxacin groups were constipation 3.5% and headache 3.3%, respectively.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on AEMCOLO use in pregnant women to inform any drug associated risks for major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation

There is no information regarding the presence of AEMCOLO in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of AEMCOLO has not been established in pediatric patients <18 years of age.

See 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).

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 commercializes and promotes several gastrointestinal products in the U.S., **Aemcolo®**, **Donnatal®**, **EnteraGam®**, and **Mytesi®**, and is planning to launch **Talicia®** in the U.S. for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[7]. 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 licensed to Salix Pharmaceuticals, Ltd. 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.

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

[7] For full prescribing information see: Aemcolo®: www.Aemcolo.com; Mytesi®: www.Mytesi.com; EnteraGam® https://bit.ly/2N3q7DW; Talicia®: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213004lbl.pdf.

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 of our launch of Talicia® , risks related to the commencement or the timing of our clinical trials with RHB-102 (Bekinda®) and ABC294640 (Yeliva®), 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 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®, Donnatal®, EnteraGam® 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 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.

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