# Press Release

## RedHill's Partner Cosmo Pharmaceuticals Successfully Completes Phase 2 Study of Rifamycin SV-MMX 600mg in IBS-D

**TEL AVIV, Israel and RALEIGH, NC, January 11, 2021,** RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or "the Company"), a specialty biopharmaceutical company, today reported that its partner, Cosmo Pharmaceuticals (SIX: COPN) ("Cosmo"), announced that it had successfully completed their Phase 2 Proof-of-Concept (POC) clinical trial of Rifamycin SV-MMX 600mg in patients with diarrhea-predominant irritable bowel syndrome (IBS-D).

As part of an exclusive license agreement between RedHill and Cosmo from October 2019 for the U.S. rights to Aemcolo® (rifamycin), RedHill maintains certain rights, including a right of first refusal, in relation to Rifamycin SV-MMX 600mg in the U.S.

Designed to address the debilitating effects of IBS-D, Rifamycin SV-MMX is delivered at a 600mg dose and with different release features to Aemcolo®. Aemcolo® is approved for travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E. coli*) in adults and promoted by RedHill for such use in the U.S.

Cosmo reported that results of the Phase 2 POC study show the achievement of statistical significance in all the study populations (ITT, FAS, m-FAS and PP) for the composite primary endpoint (substantial pain and diarrhea decrease) [OR 3.26 (1.39 – 7.67); p-value 0.0066] and for most secondary endpoints such as adequate relief of IBS-related symptoms [OR 2.18 (1.12 – 4.26); p-value 0.0227] and IBS-related bloating at the end of treatment period [OR 2.13 (1.11 – 4.07); p-value 0.0223].

"We are delighted for our partner, Cosmo, on the positive outcome of this study, which clearly demonstrates the potential for Rifamycin SV-MMX 600mg, if approved, to be an important treatment option in tackling IBS-D," **said Dror Ben-Asher, RedHill's CEO**.

**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.

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**

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[1], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[2], and **Aemcolo®** for the treatment of travelers' diarrhea in adults[3]. 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 (Yeliva®)**, a first-in-class SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and Phase 2 studies for prostate cancer and cholangiocarcinoma ongoing; (iii) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (iv) **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; (v) **RHB-107** (**upamostat**), a Phase 2-stage serine protease inhibitor with a planned Phase 2/3 study in symptomatic COVID-19 and targeting multiple other cancer and inflammatory gastrointestinal diseases; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com / https://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 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®, 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, 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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[1] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.
[2] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.
[3] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.