Press Release

RedHill Biopharma Announces $36 Million Strategic Investment by Cosmo Pharmaceuticals and U.S. Rights to Approved Travelers' Diarrhea Drug AEMCOLO

TEL-AVIV, Israel and RALEIGH, N.C., October 18, 2019 RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases, today announced that it has entered into a strategic collaboration with Cosmo Pharmaceuticals N.V. (SIX: COPN) ("Cosmo").

The strategic collaboration includes an exclusive license agreement for the U.S. rights to Aemcolo® (rifamycin) and a simultaneous private investment by Cosmo of $36.3 million in RedHill at $7.00 per American Depositary Share (ADS), representing approximately 13.5% over the closing price on October 17, 2019, with a 180-day transfer restriction.

Following this transaction, RedHill will maintain a debt-free balance sheet with approximately $59 million of cash and cash equivalents and will be well-positioned to launch RHB-105 (Talicia®)[1] for *H. pylori* infection in the U.S. with an expanded sales force, if approved by the Food and Drug Administration (FDA). The New Drug Application (NDA) for RHB-105 (Talicia®) is under priority review by the FDA, with an assigned target Prescription Drug User Fee Act (PDUFA) action date of November 2, 2019.

Aemcolo® (rifamycin), containing 194mg of rifamycin as delayed-release tablets, is a minimally absorbed antibiotic that is delivered to the colon, approved by the FDA in 2018 for the treatment of travelers' diarrhea caused by non-invasive strains of E. coli in adults ("Travelers' Diarrhea").

[1] RHB-105 (Talicia®) is an investigational new drugs, not available for commercial distribution. Talicia® is a proposed tradename and is subject to FDA review and approval.

Under the terms of the license agreement, Cosmo granted RedHill the exclusive rights to commercialize Aemcolo® in the U.S. for Traveler's Diarrhea and agreed to act as the exclusive supplier of Aemcolo®. The license agreement also provides for the grant to RedHill of certain rights related to the potential development of additional indications for Aemcolo®, as well arrangements related to other pipeline product candidates of Cosmo.

As part of the Aemcolo® license agreement, RedHill will issue Cosmo 1,714,286 ADSs at an agreed value of $12 million, as an upfront payment for the rights granted under the license, corresponding to a price per ADS of $7.00, representing approximately 13.5% over the closing price on October 17, 2019, with a 180-day transfer restriction. These ADSs are in addition to the ADSs issued to Cosmo as part of the $36.3 million investment discussed above. In addition, RedHill agreed to pay Cosmo a royalty percentage in the high twenties on net sales generated from the commercialization of Aemcolo® in the U.S. The license agreement further provides for potential regulatory and commercial milestone payments to Cosmo totaling up to $100 million. In connection with the subscription agreement, Cosmo is entitled to nominate for appointment one member to RedHill's Board of Directors.

"Cosmo is a world leader in optimized therapies for gastrointestinal diseases with a strong track record of success, expertise and commitment to changing the treatment landscape for patients" **said Dror Ben-Asher, RedHill's CEO.** "The strategic partnership with Cosmo is an important validation of RedHill's commercial capabilities, promising late-stage pipeline and overall strategy to become a leading gastrointestinal-focused company in the U.S. Cosmo's investment in RedHill ahead of the potential FDA approval and, if approved by the FDA, launch of RHB-105 (Talicia) and the addition of Aemcolo® to our GI product portfolio, positions us well for the future. We are proud to have Cosmo as our partner and look forward to a successful strategic collaboration."

Mauro Ajani, Chairman of Cosmo, said: "This deal is another big step in the transformation of Cosmo and it is closer to our history and strategy. After the deals with Medtronic, where we partnered AI and Eleview, we have now found the right U.S. partner for Aemcolo®. We are most pleased to become RedHill's largest shareholder: this stake is strategic and a demonstration of trust. We look forward to contributing towards making RedHill a rousing success."

Alessandro Della Chà, CEO of Cosmo, said: "After having received several offers, we believe we have found in RedHill the features for a long and successful collaboration: a strong and expert management team with a history of commercial success, a very interesting pipeline, a company size where our contribution could make a substantial difference and the opportunity of an equity for product deal. We are very happy to start this new partnership."

About Traveler's Diarrhea

Travelers' Diarrhea (TD) is the most common travel-related illness, affecting an estimated 10% to 40% of travelers each year[2], with approximately 70 million Americans traveling aboard of which approximately 46 million visiting developing countries[3] where TD prevalence may exceed 60%[4].

About Aemcolo®

Aemcolo® (Rifamycin) is an orally administered, minimally absorbed antibiotic approved for the treatment of Travelers' Diarrhea caused by non-invasive strains of Escherichia coli in adults. Aemcolo® is the first antibiotic engineered with Cosmo Pharmaceuticals' Multi Matrix Technology (MMX®) which allows for the colonic release of active ingredient. Aemcolo® is also being studied for IBS-D and uncomplicated diverticulitis.

Indication: Aemcolo® is indicated for the treatment of Travelers' Diarrhea caused by non-invasive strains of Escherichia 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 non-invasive strains of Escherichia coli.

Contraindications: 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®.

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%). The common adverse reactions that occurred in ~2% of Aemcolo®-treated patients in the clinical trials were constipation 3.5% and headache 3.3%. Full prescribing information for Aemcolo® is available at www.ariespharma.com.

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 clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.: **Donnatal® -** a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam® -** a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi® -** an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. RedHill's key clinical late-stage development programs include: (i) **RHB-105 (Talicia®)** for the treatment and eradication of *Helicobacter pylori* infection with a U.S. NDA submitted and accepted for priority review with a target PDUFA action date of November 2, 2019; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's

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

[3] Source: Cosmo Pharmaceuticals Investor Presentation July 2019

[4] Steffen, Robert. "Epidemiology of traveler's diarrhea." *Clinical Infectious Diseases* 41.Supplement_8 (2005): S536-S540.

disease; (iii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (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) **Yeliva® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **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 Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company that aims to become a global leader in optimized therapies for certain gastrointestinal diseases. The company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as ulcerative colitis and Crohn's disease, and colon infections. Cosmo's first product is LIALDA® / MEZAVANT® that is licensed globally to Giuliani and Shire Pharmaceuticals. Cosmo's proprietary MMX technology is at the core of the company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. For further information on Cosmo, please visit the company's website at www.cosmopharmaceuticals.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 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 be commencement or timing of our clinical trials with RHB-104, for Crohn's disease, RHB-204 for NTM infections RHB-102 (Bekinda®) and Yeliva® (ABC294640), risks related to the occurrence or timing of the RHB-105 (Talicia®) PDUFA action date, 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; (v) the Company's ability to successfully commercialize and promote

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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