Press Release

RedHill Biopharma Strengthens Partnership with Cosmo Pharmaceuticals with Manufacturing Agreements for Movantik and RHB-204

The agreements secure high-quality manufacturing capacity of Movantik® for opioid-induced constipation and RHB-204, currently in a Phase 3 study for pulmonary NTM disease

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Follows recent agreement with Cosmo for expansion of opaganib manufacturing capacity for COVID-19

TEL AVIV, Israel and RALEIGH, NC, February 18, 2021, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced agreements with Cosmo Pharmaceuticals NV (SIX: COPN) ("Cosmo") to manufacture two key products; RedHill's largest selling product in the U.S., Movantik®, and RHB-204, currently in a Phase 3 U.S. study as a stand-alone, first-line orally-administered treatment for pulmonary nontuberculous mycobacteria (NTM) disease.

"Movantik is currently our biggest commercial product. This agreement strengthens our qualified supply base and capacity moving forward and solidifies our ongoing strategic relationship with Cosmo," **said Steven Thomasian, RedHill's Vice President of Supply Chain Management**.

"We are happy to strengthen our partnership with RedHill with the manufacturing of these two important products and therefore to further expand Cosmo's production capacities and capabilities," **said Davide Malavasi, Cosmo's Head of Manufacturing.**

Movantik is the leading prescribed oral peripherally acting mu-opioid receptor antagonist (PAMORA) in the U.S. specifically designed to treat opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain[1]. OIC is the most common and debilitating gastrointestinal adverse effect associated with opioid therapy, estimated to affect between 40-80% of the millions of patients taking chronic opioid therapy each year[2].

RHB-204 is an investigational proprietary, fixed-dose oral capsule containing a combination of clarithromycin, rifabutin, and clofazimine, developed as a stand-alone first-line treatment for pulmonary NTM disease caused by *Mycobacterium avium* Complex (MAC). Although rare, the incidence and prevalence of pulmonary NTM disease are increasing in many areas of the world[3]. There were an estimated 110,000 pulmonary NTM disease patients in the U.S. in 2017, with U.S. market potential estimated at over $500 million[4]. RHB-204 has received FDA Fast Track, Orphan Drug and QIDP designations aimed at accelerating development and FDA review and extending U.S. market exclusivity to a potential total of 12 years, to be granted at the time of FDA approval.

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[5], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[6], and **Aemcolo®** for the treatment of travelers' diarrhea in adults[7]. 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-107** (**upamostat**), a serine protease inhibitor in a U.S. Phase 2/3 study for 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; (v) **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; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com / https://twitter.com/RedHillBio.

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company focused on developing and commercializing products to treat selected gastrointestinal disorders and improve endoscopy quality measures through aiding the detection of colonic lesions. Cosmo has also developed medical devices for endoscopy and has recently entered into a partnership with Medtronic for the global distribution of GI Genius™ its artificial intelligence device for use in coloscopies and GI procedures. Cosmo has licensed Aemcolo® to RedHill Biopharma for the US and has licensed Relafalk® to Dr. Falk Gmbh for the EU and other countries. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Important Safety Information About Movantik

Movantik® (naloxegol) is contraindicated in:

- Patients with known or suspected gastrointestinal (GI) obstruction and patients at risk of recurrent obstruction, due to the potential for GI perforation.

- Patients receiving strong CYP3A4 inhibitors (eg, clarithromycin, ketoconazole) because these medications can significantly increase exposure to naloxegol which may precipitate opioid withdrawal symptoms.
- Patients with a known serious or severe hypersensitivity reaction to Movantik or any of its excipients.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, irritability, and yawning, occurred in patients treated with Movantik. Patients receiving methadone as therapy for their pain condition were observed in the clinical trials to have a higher frequency of GI adverse reactions that may have been related to opioid withdrawal than patients receiving other opioids. Patients with disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. These patient (eg, multiple sclerosis, recent brain injury, Alzheimer's disease, and uncontrolled epilepsy) were not enrolled in the clinical studies. Take into account the overall risk-benefit profile when using Movantik in such patients. Monitor for symptoms of opioid withdrawal when using Movantik in such patients.

Severe abdominal pain and/or diarrhea have been reported, generally within a few days of initiation of Movantik. Monitor and discontinue if severe symptoms occur. Consider restarting Movantik at 12.5 mg once daily.

Cases of GI perforation have been reported with the use of peripherally acting opioid antagonists, including Movantik. Post marketing cases of GI perforation, including fatal cases, were reported when Movantik was used in patients at risk of GI perforation (eg, infiltrative gastrointestinal tract malignancy, recent gastrointestinal tract surgery, diverticular disease including diverticulitis, ischemic colitis, or concomitantly treated with bevacizumab). Monitor for severe, persistent, or worsening abdominal pain; discontinue if this symptom develops.

The most common adverse reactions with Movantik as compared to placebo in clinical trials were: Abdominal pain (21% vs 7%), diarrhea (9% vs 5%), nausea (8% vs 5%), flatulence (6% vs 3%), vomiting (5% vs 4%), headache (4% vs 3%), and hyperhidrosis (3% vs <1%).

Movantik® (naloxegol) is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Click here for the Medication Guide and full Prescribing Information for Movantik.

You are encouraged to report Adverse Reactions to RedHill Biopharma Inc. at 1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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, including without limitation, the risk that the agreement with Cosmo will not provide high-quality manufacturing capacity for Movantik® and RHB-204 or be sufficient to meet market demands, as well as other 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 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 preclinical studies or clinical trials (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 risk that the Company will not succeed to complete the patient recruitment; the risk that the Company will not receive the relevant data required for benefiting from the Fast Track designation; the risk that the U.S. Phase 3 clinical study evaluating RHB-204 will not be successful or, if successful, will not suffice for regulatory marketing approval without the need for additional clinical and/or other studies; (v) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia®; (vi) the Company's ability to successfully commercialize and promote Movantik®, Talicia® and Aemcolo®; (vii) the Company's ability to establish and maintain corporate collaborations; (viii) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build and sustain its own marketing and commercialization capabilities; (ix) 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; (x) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (xi) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and commercial products and its ability to operate its business without infringing the intellectual property rights of others; (xii) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xiii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiv) the effect of patients suffering adverse events using investigative drugs under the Company's Expanded Access Program; and (xv) competition from other companies and technologies within the Company's industry. 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 4, 2020. 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.

Company contact:
Adi Frish
Chief Corporate & Business Development Officer
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

Media contact (U.S.):
Bryan Gibbs
Vice President
Finn Partners
+1 212 529 2236
bryan.gibbs@finnpartners.com

[1] Since Jan 2017. IQVIA NPA
[2] Crockett, Seth D., et al. American Gastroenterological Association Institute guideline on the medical management of opioid-induced constipation, Gastroenterology 156.1 (2019): 218-226.
[3] Henkle E, *et al.* Population-based Incidence of Pulmonary Nontuberculous Mycobacterial Disease in Oregon 2007 to 2012 *Annals of the American Thoracic Society*. 2015; 12(5):642-7.
[4] Foster|Rosenblatt, 2017.
[5] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.
[6] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.
[7] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.