Press Release

RedHill Biopharma and Cosmo Pharmaceuticals to Expand Strategic Partnership with Exclusive Licensing Agreement and Manufacturing Agreement for Multiple Products

TEL-AVIV, Israel and RALEIGH, NC, August 13, 2020, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that it has entered into a binding term sheet with Cosmo Pharmaceuticals N.V. (SIX: COPN) ("Cosmo") for an exclusive licensing and manufacturing agreement for multiple products. The transaction is expected to close in the coming weeks.

Pursuant to the agreement, the companies will co-develop a novel next-generation therapy for the eradication of *H. pylori* infection. Cosmo is to receive the exclusive European rights to the new drug and will pay RedHill $7 million upon signing of the license agreement and an additional $2 million upon approval in Europe, and 30% royalties. The companies plan to jointly execute clinical trials pursuing simultaneous regulatory approvals in the U.S. and Europe, with a cost split 70% RedHill and 30% Cosmo.

Cosmo will become the exclusive worldwide manufacturer for the novel next-generation therapy for the eradication of *H. pylori* infection, Movantik® (naloxegol)[i], which RedHill recently acquired from AstraZeneca, and RHB-204 for pulmonary nontuberculous mycobacteria (NTM) infections. Cosmo will be paid €5.5 million for tech transfer, formulation and development work with respect of these products.

Additionally, Cosmo will finance the planned pivotal Phase 3 clinical study with RHB-204, which recently received FDA clearance to proceed, with a payment of $5 million upon signing of the agreement and an additional $7 million in two milestone payments. Cosmo will be entitled to 15% royalty payments.

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "We are very pleased to expand our strategic partnership with Cosmo Pharmaceuticals. This will accelerate the planned pivotal Phase 3 study with RHB-204 in pulmonary NTM infections and the development of a next-generation *H. pylori* treatment. Importantly, Cosmo has a proven track record of formulating, developing and manufacturing novel therapies for multiple countries thus ensuring high quality supply."

Alessandro Della Chà, Cosmo's Chief Executive Officer, said: "We are happy we have found new ways to expand our relationship with our partner RedHill and now we are eager to start working on these multiple opportunities for the benefit of both companies, With these deals we will simultaneously develop a new next-generation product for *H. pylori* eradication, expand our manufacturing franchise and help RedHill accelerate the clinical development of RHB-204".

About RHB-204

RHB-204 is a proprietary, fixed-dose oral capsule containing a combination of clarithromycin, rifabutin, and clofazimine, developed for the treatment of pulmonary NTM infections caused by *Mycobacterium avium* Complex (MAC). RHB-204 was granted QIDP designation and is eligible for an expedited development pathway and priority review, as well as a total of eight years of U.S. market exclusivity, if approved. RedHill has also submitted to the FDA an Orphan Drug Designation application for RHB-204, which, if granted, will extend U.S. market exclusivity to a total of 12 years. RHB-204 is also covered by U.S. patents which extend patent protection until 2029 and a pending U.S. patent application which, if allowed, could extend RHB-204 patent protection until 2041.

About Movantik®

RedHill acquired the global rights, excluding Europe, Canada and Israel, to Movantik® for the treatment of opioid induced constipation from AstraZeneca in April 2020 and immediately initiated promotion in the U.S. with its expanded sales force.

Movantik® is a proprietary once-daily oral PAMORA approved by the U.S. Food and Drug Administration for the treatment of 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. Movantik® is the first oral PAMORA approved in the U.S. for the treatment of OIC and is recommended by the American Gastroenterological Association (AGA) guidelines[ii] and the National Comprehensive Cancer Network (NCCN) guidelines. Movantik® is part of the exclusive worldwide license agreement announced in 2009 between AstraZeneca and Nektar Therapeutics. It was developed using Nektar's oral small-molecule polymer conjugate technology. Movantik® was first approved in 2014 and launched in the U.S. by AstraZeneca and Daiichi Sankyo in 2015. Further information about Movantik® is available at: www.Movantik.com.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal diseases. RedHill promotes the gastrointestinal drugs, **Movantik®** for opioid-induced constipation in adults[i], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[iii] and **Aemcolo®** for the treatment of travelers' diarrhea in adults[iv]. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (ii) **opaganib (Yeliva®)**, a first-in-class SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and ongoing Phase 2 studies for prostate cancer and cholangiocarcinoma; (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-106**, an encapsulated bowel preparation, and (vi) **RHB-107**, a

Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases and is also being evaluated for COVID-19. More information about the Company is available at www.redhillbio.com.

IMPORTANT SAFETY INFORMATION ABOUT MOVANTIK

- **MOVANTIK may cause serious side effects, including:**
  - **Opioid withdrawal.** You may have symptoms of opioid withdrawal during treatment with MOVANTIK, including sweating, chills, diarrhea, stomach pain, anxiety, irritability, and yawning. Patients taking methadone to treat their pain may be more likely to experience stomach pain and diarrhea. Tell your doctor if you have any of these symptoms
  - **Severe Stomach Pain and/or Diarrhea.** This can happen within a few days of starting MOVANTIK and can lead to hospitalization. If either of these side effects occurs, stop taking MOVANTIK and call your doctor immediately
  - **Tear in your stomach or intestinal wall (perforation).** Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that gets worse or does not go away, stop taking MOVANTIK and get emergency medical help right away
- **Do not take MOVANTIK if you:**
  - Have a bowel blockage (intestinal obstruction) or have a history of bowel blockage
  - Are allergic to MOVANTIK or any of the ingredients in MOVANTIK
- MOVANTIK can interact with other medicines and cause side effects, including opioid withdrawal symptoms (see symptoms above). Tell your doctor or pharmacist before you start or stop any medicines during treatment with MOVANTIK
- **Before you take MOVANTIK, tell your doctor about all of your medical conditions, including if you:**
  - Have any stomach, bowel (intestines) problems, including inflammation in parts of the large intestine (diverticulitis), or inflammation and injury of the intestines caused by reduced blood flow (ischemic colitis)
  - Have had recent surgery on the stomach or intestines
  - Have any kidney, or liver problems
  - Are pregnant or plan to become pregnant. Taking MOVANTIK during pregnancy may cause opioid withdrawal symptoms in you or your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with MOVANTIK

- Are breastfeeding or plan to breastfeed. It is not known if MOVANTIK passes into your breast milk. Taking MOVANTIK while you are breastfeeding may cause opioid withdrawal in your baby. You and your healthcare provider should decide if you will take MOVANTIK or breastfeed. You should not breastfeed if you take MOVANTIK

- **Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect the way MOVANTIK works**
- **If you stop taking your opioid pain medicine, stop taking MOVANTIK and tell your doctor**
- **Avoid eating grapefruit or drinking grapefruit juice during treatment with MOVANTIK**
- **The most common side effects of MOVANTIK include: Stomach (abdomen) pain, diarrhea, nausea, gas, vomiting, headache, and excessive sweating**

APPROVED USE FOR MOVANTIK

MOVANTIK is a prescription medicine used to treat constipation that is caused by prescription pain medicines called opioids, in adults with long-lasting (chronic) pain that is not caused by active cancer.

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 include, without limitation, the risk of a delay in the closing of the exclusive licensing and manufacturing agreement with Cosmo, the risk that it will close on different terms than the terms of the binding term sheet and the risk that will not close at all, 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 Movantik®, Talicia® and Aemcolo® ; (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 and sustain 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 commercial products 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; and (xiv) 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.

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[i] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com..
[ii] Crockett, Seth D., et al. American Gastroenterological Association Institute guideline on the medical management of opioid-induced constipation, *Gastroenterology* 156.1 (2019): 218-226.
[iii] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.
[iv] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.