



Cosmo Pharmaceuticals Strengthens Partnership with RedHill Biopharma with Manufacturing Agreement for Movantik, RHB-204 and Opaganib

Dublin, Ireland – 18 February 2021: Cosmo Pharmaceuticals NV (SIX: COPN) today announced an agreement with RedHill Biopharma Ltd. (Nasdaq: RDHL) (“RedHill”) to manufacture three key products; Movantik® (RedHill’s largest selling product in the U.S.), RHB-204 (currently in a Phase III U.S. study as a stand-alone first-line treatment for pulmonary nontuberculous mycobacteria (NTM) disease) and opaganib (a new, orally-administered, chemical entity currently in a global Phase II/III study for treatment of COVID-19 pneumonia). These agreements provide secure high-quality manufacturing capacity for all three products.

“Movantik is currently our biggest commercial product, and opaganib and RHB-204 are key Phase III-stage development programs for indications with strong and urgent unmet medical need. These agreements strengthen our qualified supply base and capacity moving forward and solidify our ongoing strategic relationship with Cosmo,” said Reza Fathi, PhD., RedHill’s Senior VP, R&D.

“We are happy to strengthen our partnership with RedHill with the manufacturing of these three 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 pain¹. 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.

RHB-204 is RedHill’s 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. There were an estimated 110,000 pulmonary NTM disease patients in the U.S. in 2017, with U.S. market potential estimated at over US\$ 500 million. 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.

Opaganib is being evaluated by RedHill as a treatment for COVID-19 pneumonia in a global Phase II/III study and has demonstrated positive safety and efficacy top-line data from a U.S. Phase II study. Opaganib, a new chemical entity, is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with demonstrated dual anti-inflammatory and antiviral activity that targets a host cell component of viral replication, potentially minimizing the likelihood of viral resistance. It has also shown anticancer activity and has the potential to target multiple oncology,

¹ Since Jan 2017. IQVIA NPA

viral, inflammatory, and gastrointestinal indications.

Opaganib received Orphan Drug designation from the U.S. FDA for the treatment of cholangiocarcinoma and is also being evaluated in a Phase IIa study in advanced cholangiocarcinoma and in a Phase II study in prostate cancer.

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company focused on developing and commercialising 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 colonoscopies and GI procedures. Cosmo has licensed Aemcolo® to Red Hill Biopharma Ltd. 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

Calendar

2021 Credit Suisse London Global Healthcare Conference	March 2-4, 2021
Full Year Results 2020	March 26, 2021
Annual General Meeting, Amsterdam	May 28, 2021

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