



## **Cosmo Pharmaceuticals announces RedHill's Approval of Compassionate Use of Opaganib for the treatment of COVID-19 in Italy**

**Dublin, Ireland – April 6, 2020** – Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced that its participated company RedHill Biopharma (NASDAQ: RDHL) – with Cosmo's support - has obtained approval by the Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani (the Italian National Institute for Infectious Diseases) for the immediate compassionate use of its proprietary investigational drug Opaganib (Yeliva®, ABC294640) to treat patients with confirmed coronavirus (COVID-19) infection with life-threatening clinical conditions.

Opaganib, a new chemical entity, is a first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anticancer, anti-viral and anti-inflammatory activities, targeting multiple oncology, inflammatory and gastrointestinal indications. Pre-clinical data have demonstrated both anti-viral and anti-inflammatory activities of Opaganib, with the potential to reduce lung inflammatory disorders, such as pneumonia, and mitigate pulmonary fibrotic damage. Several prior pre-clinical studies support the potential role of SK2 in the replication-transcription complex of positive-strand single-stranded RNA viruses, similar to coronavirus, and its inhibition may potentially inhibit viral replication. Pre-clinical in vivo studies have demonstrated that Opaganib decreased fatality rates from influenza-virus infection and ameliorated *Pseudomonas aeruginosa*-induced lung injury<sup>1</sup>.

A total of 131 subjects have been dosed with Opaganib to date in ongoing and completed Phase 1 and Phase 2 clinical studies in oncology indications in the U.S., in pharmacokinetic studies in healthy volunteers in the U.S., and under the existing FDA-approved expanded access requests from physicians for individual oncology patients, establishing safety and tolerability in humans both in the U.S. and ex-U.S.

Initially, 140 patients are planned to be treated in three major hospitals in Northern Italy, one of the current major epicenters of the pandemic.

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<sup>1</sup> Xia C. et al. Transient inhibition of sphingosine kinases confers protection to influenza A virus infected mice. *Antiviral Res.* 2018 Oct; 158:171-177. Ebenezer DL et al. *Pseudomonas aeruginosa* stimulates nuclear sphingosine-1-phosphate generation and epigenetic regulation of lung inflammatory injury. *Thorax.* 2019 Jun;74(6):579-591.

A compassionate use program is ongoing in Israel, where Opaganib has been already administered to the first patient at a leading hospital. Discussions are also ongoing for a clinical development program as well as potential expanded access of Opaganib for COVID-19 in the U.S.

Cosmo and RedHill have agreed that Cosmo will become the exclusive or main commercial supplier in the future, subject to Opaganib demonstrating positive clinical results, negotiation of final terms and the necessary regulatory approvals. Accordingly, the parties have initiated the manufacturing tech transfer process.

“The approved Opaganib expanded access program allows physicians in major hospitals in Italy to treat patients at high risk of developing pneumonia and those with pneumonia, including acute respiratory distress syndrome, secondary to SARS-CoV-2 infection,” said **Mark L. Levitt, MD, Ph.D., medical director at RedHill**. “RedHill is working diligently to evaluate the potential of Opaganib as a treatment for COVID-19 to help patients worldwide in urgent need of a treatment option. I would like to thank our partners at Cosmo Pharmaceuticals for their immense assistance supporting the process in Italy.”

**Alessandro Della Chà, CEO of Cosmo**, stated: “We are proud we have been able to help RedHill, of which we own a substantial stake, bring to COVID-19 patients its promising investigational product in these very challenging times. We hope Opaganib will prove to be an effective treatment against the pandemic.”

#### **About Cosmo Pharmaceuticals**

Cosmo is a specialty pharmaceutical company focused in treating selected Gastrointestinal Disorders and Endoscopy. The Company’s proprietary clinical development pipeline specifically addresses innovative treatments for IBD, Colonic Infections and 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 its novel Artificial Intelligence device to be used in colonoscopies and GI procedures. Further, Cosmo has licensed Aemcolo™ to Red Hill Biopharma and is the licensee for U.S. of the novel agent for procedural sedation, remimazolam, which it has sub-licensed to Acacia. For additional information on Cosmo and its products please visit the Company’s website: [www.cosmopharma.com](http://www.cosmopharma.com)

#### **Calendar**

Annual General Meeting, Amsterdam	May 28, 2020
Jefferies Healthcare Conference, London	June 2-4, 2020

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