



## **Cosmo's Partner RedHill announces approval of Talicia® for the treatment of H. Pylori in adults in the USA**

**Dublin, Ireland – November 4, 2019** – Cosmo Pharmaceuticals N.V. (SIX: COPN) today informs that its partner RedHill Biopharma (NASDAQ: RDHL, Tel-Aviv Stock Exchange: RDHL) today announced that the U.S. Food and Drug Administration (FDA) has approved Talicia® (omeprazole magnesium<sup>1</sup> 10.3 mg, amoxicillin 250 mg and rifabutin 12.5 mg) delayed-release capsules for the treatment of Helicobacter pylori (H. pylori) infection in adults.

Talicia® is the only rifabutin-based therapy approved for the treatment of H. pylori infection and is designed to address the high resistance of H. pylori bacteria to current clarithromycin-based standard-of-care therapies. It is estimated that H. pylori resistance to clarithromycin more than doubled between 2009-2013.

Talicia® is eligible for 8 years of U.S. market exclusivity under QIDP designation, in addition to patent protection extending until 2034.

RedHill plans to launch Talicia®<sup>1</sup> in the U.S. in Q1/2020 for the treatment for H. pylori infection in adults, targeting more than two million patients estimated to be treated for H. pylori infection annually.

Cosmo announced on October 18, 2019, that it had taken a 19.56% stake in RedHill and had licensed out Aemcolo to RedHill.

### **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 is the licensee for US of the novel agent for procedural sedation, Remimazolam. For additional information on Cosmo and its products please visit the Company's website: [www.cosmopharma.com](http://www.cosmopharma.com)

---

<sup>1</sup> Each delayed-release capsule contains omeprazole 10 mg (equivalent to 10.3 mg omeprazole magnesium), amoxicillin 250 mg, and rifabutin 12.5 mg.

## 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 proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S, **Donnatal**<sup>®</sup>, **EnteraGam**<sup>®</sup> and **Mytesi**<sup>®</sup>, and is planning to launch **Aemcolo**<sup>®</sup> and **Talicia**<sup>®</sup> in the U.S. On November 2, 2019, the FDA approved Talicia<sup>®</sup> for marketing in the U.S. for the treatment and of *Helicobacter pylori* (*H. pylori*) infection. RedHill's key clinical late-stage development programs include: (i) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102 (Bekinda)**<sup>®</sup>, with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **ABC294640 (Yeliva)**<sup>®</sup>, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **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](http://www.redhillbio.com)

## Calendar

Credit Suisse Small & Mid Cap Conference, Zurich	November 13, 2019
Jefferies Global Health Care Conference, London	November 20, 2019
FY Results	March 2020
Annual General Meeting	May 2020

## Contact:

Niall Donnelly, Chief Financial Officer & Head of Investor Relations  
Cosmo Pharmaceuticals N.V.  
Tel: +353 1 817 03 70  
[ndonnelly@cosmopharma.com](mailto:ndonnelly@cosmopharma.com)

Some of the information contained in this press release contains forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cosmo undertakes no obligation to publicly update or revise any forward-looking statements.

This communication is not an offer of securities of any issuer. Securities may not be offered or sold in the United States absent registration or an exemption from the registration requirement of the US Securities Act of 1933.

This press release constitutes neither an offer to sell nor a solicitation to buy securities and it does not constitute a prospectus within the meaning of article 652a and/or 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any similar document. The offer will be made solely by means of, and on the basis of, a securities prospectus to be published. An investment decision regarding the securities to be publicly offered should only be made on the basis of the securities prospectus.

This press release is made to and directed only at (i) persons outside the United Kingdom, (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"), and (iii) high net worth individuals, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order. Any person who is not a relevant person should not act or rely on this press release or any of its contents.

This press release does not constitute an "offer of securities to the public" within the meaning of Directive 2003/71/EC of the European Union (the "Prospectus Directive") of the securities referred to in it (the "Securities") in any member state of the European Economic Area (the "EEA"). Any offers of the Securities to persons in the EEA will be made pursuant to an exemption under the Prospectus Directive, as implemented in member states of the EEA, from the requirement to produce a prospectus for offers of the Securities.