



Cosmo announces FDA grants orphan-drug designation of rifamycin for treatment of pouchitis

Dublin, Ireland – 20 October 2022. Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) announces that the FDA has granted the orphan-drug designation request of rifamycin for treatment of pouchitis.

Patients with ulcerative colitis (UC) may require removal of their colon and rectum (proctocolectomy), and the surgical creation of an ileal pouch to aid stool retention (ileal pouch-anal anastomosis or IPAA). Pouchitis is a nonspecific inflammatory condition and the most common complication of an IPAA, with a reported incidence rate between 23% and 59% in patients with UC.

Patients with pouchitis can present with a wide range of clinical presentations, including increased stool frequency, urgency, tenesmus, incontinence, nocturnal seepage, abdominal cramping, and abdominal discomfort. Although bloody bowel movements are uncommon in typical pouchitis, patients can have iron-deficient anaemia. Patients with severe pouchitis occasionally present with fever, dehydration, and malnutrition, which may require hospitalization.

Patients with pouchitis are known to respond to off-label antibiotic therapy, although there is not yet an approved antibiotic product. Cosmo has conceived and developed a novel formulation to deliver Rifamycin SV, an antibiotic belonging to the Ansamycin family, to treat pouchitis. The granting of the Orphan Drug Designation (ODD) by the FDA is an essential step to streamline and accelerate the development of a much-needed treatment.

Alessandro Della Chà, CEO of Cosmo, said: *“The grant of the ODD for Rifamycin from the FDA to treat pouchitis is another major advancement of our GI pipeline of innovative products. We will now swiftly pursue the clinical development of this new candidate”.*

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda®, Uceris®/Cortiment® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. 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. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company’s website: www.cosmopharma.com

Upcoming Calendar of Events

Credit Suisse Equity Forum Switzerland	November 16, 2022
Jefferies 2022 London Healthcare Conference	November 15-17, 2022
Deutsches Eigenkapitalforum, Frankfurt	November 28-30, 2022

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