



Cosmo announces acceptance of NDA submission of Cortiment® MMX® in Japan

Dublin, Ireland – 28 June 2022: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) announced that Ferring, our partner for Cortiment® MMX® (budesonide), submitted the NDA for Japan on June 23, 2022, and the application has been accepted by PMDA (Pharmaceuticals and Medical Devices Agency). The review is expected to last approximately a year.

Cortiment® is a once-daily oral tablet formulation which delivers budesonide directly to the lumen of the colon. Budesonide is a corticosteroid that has mainly topical anti-inflammatory activity. It is prescription-only and is used to help get active, mild to moderate Ulcerative Colitis under control (induce remission) and may help relieve the symptoms of ulcerative colitis.

Cortiment® has been developed by Cosmo. In 2015, Cosmo had signed a licensing agreement with Ferring Pharmaceuticals, granting Ferring the rights to Cortiment® MMX® for Japan. Ferring is the licensee in the EU and the rest of the world. In the United States, where the product is available as Uceris®, the licensee is Bausch.

In Japan it is believed that as many as 180,000 people suffer from Ulcerative Colitis, a form of inflammatory bowel disease (IBD) that produces inflammation and ulcers along the inside of the colon. The inflammation can interfere with the normal function of the colon, often causing cramping, bloating, diarrhoea, bleeding, fatigue, weight loss and frequent bowel movements, which may also strongly affect quality of life.

The approved dosing regimen for adult patients is one 9 mg tablet taken once daily for up to 8 weeks. In phase III studies, 2.4 to 3.9 times more patients achieved clinical remission and mucosal healing with Cortiment® compared to placebo, and no clinically significant glucocorticosteroid side effects were seen versus placebo after eight weeks of treatment (CORE I study and CORE II study respectively).

Alessandro Della Chà, Chief Executive Officer, said: *“We firmly believe that Cortiment® MMX® will play an increasingly important role in treating Ulcerative Colitis patients in Japan. Ferring is one of the most experienced companies in inflammatory bowel disease world-wide and we are pleased to see Ferring making progress in Japan”.*

About Cortiment® MMX®

Cortiment® contains budesonide, a locally acting corticosteroid in a novel, patented, oral tablet formulation, which utilizes MMX® multi-matrix technology and is designed to result in the controlled release and distribution of budesonide throughout the length of the colon. Budesonide has mainly topical anti-inflammatory activity and due to its high first pass metabolism, it has low system bioavailability. Budesonide using MMX® technology may be marketed under another name in some countries.

About Ulcerative Colitis

Ulcerative Colitis is a form of inflammatory bowel disease (IBD) that produces inflammation and ulcers along the inside of the colon. The inflammation can interfere with the normal function of the colon, often causing cramping, bloating, diarrhoea, bleeding, fatigue, weight loss and frequent bowel movements, which may also strongly affect quality of life. It is believed that as many as 1.5 million people in the European Union and 2.1 million people in the total European population suffer from Ulcerative Colitis.



Ulcerative Colitis is a chronic relapsing-remitting illness for which there is no known cure, but with appropriate treatment patients can manage their symptoms. However, it is estimated that up to 30% of patients with mild or moderate Ulcerative Colitis do not respond to aminosalicylate (5-ASA) drugs and require a different or add on therapy. Patients refractive to treatment with 5-ASA drugs typically receive a course of a systemically absorbed corticosteroid, the success of which may be limited by significant side effects. For moderate to severe cases of Ulcerative Colitis, immunosuppressant drugs or biologic drugs may be prescribed. If the condition does not respond to pharmaceutical therapy and the symptoms are severe, the patient may be referred for surgery.

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 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. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Upcoming Calendar of Events

Half-Year 2022 Report	July 28, 2022
Commerzbank and ODDO BHF Conference	September 6-8, 2022
Investora Conference, Zurich	September 21-22, 2022
Credit Suisse Equity Forum Switzerland	November 15-17, 2022
Jefferies 2022 London Healthcare Conference	November 15-17, 2022

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