Cosmo Pharmaceuticals Files Marketing Authorization Application for Methylene Blue MMX 200 mg Tablets with European Medicines Agency

Dublin – February 12, 2019 – Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced the filing of a Marketing Authorization Application for Methylene Blue MMX 200 mg tablets with the European Medicines Agency (EMA). Methylene Blue MMX is intended as an aid for the visualization and the detection of lesions in subjects undergoing colonoscopy.

The dossier has been granted the Centralized Authorization Procedure in light of the interests of the patients. This means that, if approval will be granted, such approval will be automatically effective in all EU Member States. The review procedure is expected to be concluded within 12 months.

"While we wait for the outcome of the FDA appeal, we continue to pursue the objective of bringing Methylene Blue MMX to other markets. The EMA filing is another positive step toward bringing this innovative drug to patients and endoscopists," said Alessandro Della Chà, CEO Cosmo Pharmaceuticals.

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company that aims to become a global leader in the field of optimized therapies for selected Gastrointestinal Disorders and Endoscopic Procedures. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as Ulcerative Colitis and Crohn's Disease, and Colon Infections. In addition, the Company has developed and launched Eleview, a medical device for polyp and adenoma excision, in the U.S. and it has filed the NDA for Methylene Blue MMX, a diagnostic drug for the detection of lesions during colonoscopy. In addition, new chemical entities are being developed by its associate company Cassiopea S.p.A. for the topical treatment of skin diseases. Cosmo's MMX drugs already on the market are Lialda/ Mezavant/Mesavancol, a treatment for IBD that is licensed globally to Giuliani and Shire Limited and Uceris, the first glucocorticosteroid indicated for the induction of remission in active, mild to moderate Ulcerative Colitis, licensed in US to Santarus/Salix/Valeant and in the Rest of the World to Ferring as Cortiment. The FDA has also recently approved Aemcolo, Cosmo's first antibiotic for the treatment of Travelers' Diarrhea. Cosmo's proprietary MMX technology is at the core of the Company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. The technology is designed to deliver active ingredients in a targeted manner in the colon. For further information on Cosmo, please visit the Company's website: www.cosmopharma.com

Next events

Full-year results 2018 reporting	March 29, 2019
Annual General Meeting	May 2019

Contact:

John Manieri, Head of Investor Relations
Cosmo Pharmaceuticals N.V.
Tel: +353 1 817 03 70
jmanieri@cosmopharma.com