Cosmo Pharmaceuticals Methylene Blue MMX Regulatory Update: Type A Meeting outcome – Next steps

Dublin, Ireland – September 13, 2018 – Cosmo Pharmaceuticals N.V. (SIX: COPN) today provided a regulatory update after receipt of the official meeting minutes from the requested July 2018 Type A Meeting with the FDA Medical Imaging Division to discuss the path forward for MB MMX, a product for visualization of lesions in patients undergoing colonoscopy to improve overall detection of adenomas and carcinomas.

Cosmo requested the Type A meeting to address the Complete Response Letter for the MB MMX NDA. According to the minutes, while some of the issues have been resolved, some disagreement with the review division remains.

Cosmo will pursue the Formal Dispute Resolution process and file an appeal above the Medical Imaging Division level, to the Office of Drug Evaluation IV (ODE IV) in the Center for Drug Evaluation and Research (CDER) in the next days.

Upon receipt of the appeal, ODE IV is expected to act within 30 days to either grant or deny the appeal or request a meeting or additional information. Cosmo will continue to promptly provide updates on the process.

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 colon cancer. 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*. 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

Jefferies Global Healthcare Conference	November 2018 in London
Full-year results 2018 reporting	March 2019
Annual General Meeting	May 2019

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