Cosmo Pharmaceuticals announces denial of Methylene Blue MMX appeal and beginning of activity to start second phase III trial

Dublin, Ireland – March 12, 2019 - Cosmo Pharmaceuticals N.V. (SIX: COPN) today provided a regulatory update for Methylene Blue MMX, an investigational new drug product for visualization of lesions in patients undergoing colonoscopy to improve overall detection of adenomas and carcinomas.

The FDA Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) has denied Cosmo's last appeal, while stating again that the completed phase III clinical trial has been successful and statistically significant without deviation from the protocol. According to the FDA, since Methylene Blue MMX is not intended to cure a disease but help the prevention of colorectal cancer and will likely be taken by millions of patients undergoing colonoscopy, a phase III confirmatory trial is needed to approve the drug.

“While we are very disappointed about this outcome as the agreed Special Protocol Assessment (SPA) provided for a single trial, the time spent in the dispute resolution process has been essential in helping both us and the Agency fully understand the potential of Methylene Blue MMX,” said Alessandro Della Chà, CEO of Cosmo Pharmaceuticals. “For this reason, we will not pursue further appeals. We intend now to present a new clinical plan with different endpoints that will take into account the excellent and undisputed findings of the completed phase III. Methylene Blue MMX has already proven to be efficacious and to have the potential to be a tremendous help to increase the performance of endoscopists. Upon agreement with the Agency on the new trial design we will start immediately the confirmatory phase III trial to bring this product as quickly as possible to the market.”

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

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