Cosmo Pharmaceuticals Receives Complete Response Letter from the FDA on Methylene Blue MMX NDA

Dublin – May 23, 2018 – Cosmo Pharmaceuticals NV (SIX: COPN) today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its submission of a New Drug Application (NDA) for Methylene Blue MMX, which is intended as a visualization aid to increase detection of lesions in the colon.

The CRL is consistent with the preliminary feedback Cosmo announced on May 9, 2018, stating that the FDA identified unspecified deficiencies that preclude the continuation of the discussion of labeling and post-marketing requirement/commitments. The CRL states that the FDA has determined it cannot approve the NDA in its present form and provides recommendations needed for resubmission.

The FDA did not raise any safety or manufacturing concern. The CRL states instead that, although the outcome of the phase III trial has translated in a statistically significant outcome, the outcome is not sufficiently "*robust*" and thus recommends Cosmo to provide confirmation of effectiveness with a second phase III trial.

"*We are extremely disappointed for all patients looking for more effective colonoscopy and we strongly disagree with the FDA conclusions,*" said Alessandro Della Chà, chief executive officer of Cosmo Pharmaceuticals NV. "*This decision fails to consider the benefit-risk of Methylene Blue MMX and the high unmet medical need. We believe the concerns raised by the FDA are fully addressable, thus we will work to have a meeting with the FDA as quick as possible.*"

Cosmo does not expect its guidance for 2018 to change at this point in time because, whilst there might not be Methylene Blue MMX revenues in this year, there also won't be the associated product launch and sales force costs.

About Methylene Blue MMX
Methylene Blue MMX is a novel application of methylene blue, a coloring agent that is used to stain the mucosa to discover pre-cancerous lesions and polyps in the colon. The objective is to deliver methylene blue along the length of the entire colon via the MMX™ technology thus enabling endoscopists to better detect pre-cancerous and cancerous lesions and polyps throughout the entire colon.

In late 2016, Cosmo completed an extensive phase III trial in 18 leading centers in North America and Europe. The full analysis and per protocol set included 1,205 and 1,137 subjects, respectively. The primary endpoint was superiority over standard of care, which is high definition white light endoscopy. The trial met the primary endpoint

by demonstrating that 17.7% more patients with adenomas were detected than in the standard of care arm (p value 0.009).

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. 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 Eleview™, a medical device for polyp excision and is developing Methylene Blue MMX®, a product for the detection of colon cancer and has a large shareholding in Cassiopea S.p.A., a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products. Cosmo's MMX® products that have reached the market are Lialda®/Mezavant®/Mesavancol®, a treatment for Ulcerative Colitis that is licensed globally to Nogra and Shire Limited and Uceris®, the first glucocorticosteroid indicated for the induction of remission in active, mild to moderate Ulcerative Colitis, licensed in the USA to Santarus/Salix/Valeant and in the Rest of the World to Ferring. 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

Financial Calendar

AGM in Amsterdam 30 May 2018

Contact

John Manieri, Head of Investor Relations
Cosmo Pharmaceuticals N.V.
Tel: +353 (1) 8170 370
jmanieri@cosmopharma.com

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