Cosmo Pharmaceuticals Methylene Blue MMX Regulatory Update: Type A Meeting Request filed to FDA

Dublin – June 28, 2018 – Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced that it has submitted a Type A Meeting Request and Briefing Document to the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) dated May 21, 2018. The purpose of the meeting is to confer upon issues identified by the FDA in the CRL and to ask the Agency for reconsideration of the submitted NDA. The meeting should take place in about 30 days; thus, Cosmo expects it in late July/beginning of August 2018.

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
Half-Year Results July 26, 2018

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