FDA accepts new drug application submission for Cosmo Pharmaceutical's Rifamycin SV MMX and sets PDUFA date for November 16, 2018

Dublin – May 18, 2018 – Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced that it has been notified by the U.S. Food and Drug Administration that the Agency has accepted the filing of its New Drug Application (NDA) seeking market approval for Rifamycin SV MMX in the United States. The acceptance of the NDA reflects the FDA's determination that the application is sufficiently complete to permit a priority review cycle of 6 months, beginning from the filing date, confirming the Prescription Drug User Fee Act (PDUFA) date on November 16, 2018 to complete its review.

The FDA stated that their internal mid-cycle review meeting is scheduled on June 26, 2018 and plans to communicate a proposed labelling and, if necessary, any post marketing requirement/commitment requests by August 23, 2018, provided that there are no major deficiencies identified during the review.

"*The acceptance of our NDA filing for Rifamycin was a long awaited-for event. Because of the priority review, the timeline will unfold very quickly and we are preparing ourselves to launch a much needed-for new antibiotic for colonic infections, which we believe has unique features*" said Alessandro Della Chà, Chief Executive Officer of Cosmo Pharmaceuticals. "*We look forward to productive interactions with the FDA to quickly satisfy unmet medical needs in the GI space."*

About Rifamycin SV MMX: Rifamycin SV MMX is a pharmaceutical product candidate employing rifamycin SV engineered with Cosmo Pharmaceuticals' MMX® technology. Rifamycin SV MMX is a broad spectrum, semi-synthetic, orally non-absorbable antibiotic which can be used for the treatment of bacterial infections of the colon such as traveler's diarrhea. The application of MMX® technology to rifamycin SV allows the antibiotic to be delivered directly into the colon, avoiding unwanted effects on the beneficial bacterial flora living in the upper portions of the gastro-intestinal tract. The specific dissolution profile of Rifamycin SV MMX tablets is thought to increase the colonic disposition of the antibiotic so that an optimized intestinal concentration is achieved thus abating its systemic absorption in the small intestine.

Phase III clinical trials of Rifamycin SV MMX in traveler's diarrhea have been completed in the US and EU. The Phase III program demonstrated Rifamycin SV MMX's superiority as compared to placebo (p-value = 0.0008) and its non-inferiority as compared to Ciprofloxacin (p-value = 0.0033), the worldwide standard of care.

A Marketing Authorization Application is under evaluation in several European countries under a DCP application promoted by Falk Pharma, our licensee for Europe and some other territories.

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

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