Cosmo announces successful outcome of phase III clinical trial for Rifamycin SV MMX®

Dublin – 6 June 2016 – Cosmo Pharmaceuticals N.V. (SIX: COPN) announced that all primary and secondary clinical endpoints were attained in the phase III pivotal trial of Rifamycin SV MMX® for Infectious Colitis run by its licensee, Dr. Falk Pharma. This was the second pivotal trial and completes the data set necessary for the filing of a new drug application in the USA and in the EU.

Rifamycin SV MMX® is an antibiotic that belongs to the Ansamycin family, i.e. a sister molecule to Rifaximin and brings substantial innovation to the gastrointestinal field. First of all, it is a New Chemical Entity (NCE) in the USA. Second of all, it is not systemically absorbable when taken orally. Third of all, because of the MMX® technology, it is ideal for the treatment of infections in the colon as its release mechanism provides topical delivery throughout all colonic districts. Jointly under the NCE rules and the GAIN act to help the introduction of new antibiotics, Rifamycin SV MMX® will, once approved, benefit of 10 years of regulatory exclusivity in the USA.

The phase III clinical study with Rifamycin SV MMX® was run by Dr. Falk Pharma. It enrolled more than 800 patients in an international multi-centre, randomized, double-blind, non-inferiority trial against Ciprofloxacin to assess the efficacy and safety of Rifamycin SV MMX® 400 mg (two oral tablets of 200 mg each) taken twice daily (800 mg total daily dose) for three days in the treatment of patients with travellers' diarrhoea.

Together with the US trial originally run by Santarus, more than 1,200 patients have been treated with the drug experiencing no remarkable adverse events.

Additional information about the Phase III study design is available from *clinicaltrials.gov*. A detailed analysis of the data will be presented at Cosmo's R&D day which is scheduled to occur within the next few weeks. A separate invitation to this event will follow.

Dr. Falk Pharma is Cosmo's licensee for the EU and Australia, Cosmo has kept the rights for the USA, Latin America and Asia.

Currently Dr. Falk Pharma is also running clinical trials targeting Uncomplicated Diverticulitis and Cosmo intends to shortly file for authorization of a new formulation for phase II trials in IBS-D that will be conducted in Europe for the purpose of global registration.

Alessandro Della Chà, CEO of Cosmo, commented: "This is a result we have waited for a long time and it was well worth waiting for. In the USA Rifamycin is a new

chemical entity, one of few new antibiotics, something the patients really need because of the well-known resistance issues. We believe it has great potential and it is probably our most undervalued asset. We will now start building our own US commercial organization to first market SIC 8000 (to be marketed under the brand name Eleview™), and once they are approved, Rifamycin SV MMX® and Methylene Blue MMX®, whose data we also expect shortly. These three products in the US will give us a uniquely positioned portfolio of products in the endoscopy and gastrointestinal field. By marketing them ourselves, we will be able to retain a larger part of the value."

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

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