# Cosmo announces its licensee Dr. Falk Pharma received approval in the European Decentralized Procedure for Relafalk (Rifamycin SV MMX) in Travelers' Diarrhea

**Dublin, Ireland - November 28, 2018 -** Cosmo Pharmaceuticals N.V. (SIX: COPN) announces that its licensee Dr. Falk Pharma has received today approval in the European Decentralized Procedure (DCP) for Relafalk (Rifamycin SV MMX) for the treatment of Travelers' Diarrhea. This approval follows the approval of AEMCOLO (Rifamycin SV MMX) by the FDA on November 16 for the same indication.

The DCP concerned the following Member States: Germany, United Kingdom, Spain, Denmark, Greece, Finland, Hungary, Norway, Portugal, Poland, Sweden and Bulgaria.

"We are very happy with this further approval, which opens up the European Market for the exploitation of this MMX oral dosage form of the antibiotic Rifamycin SV in the gastrointestinal infections. We are thankful to our partner Dr. Falk Pharma for the successful outcome of the DCP", said Alessandro Della Chà, CEO of Cosmo Pharmaceuticals N.V.

**About RELAFALK**
Relafalk (Rifamycin SV MMX) is an orally administered, minimally absorbed antibiotic approved for the treatment of Travelers' Diarrhea caused by non-invasive strains of Escherichia coli in adults. Relafalk is the first antibiotic engineered with Cosmo Pharmaceuticals' Multi Matrix Technology (MMX®) which allows for the colonic release of active ingredient. Relafalk was approved based on data from two randomized, multi-center, controlled Phase 3 clinical trials. In both trials Relafalk was dosed at 400mg twice daily for three days. Relafalk demonstrated superiority to placebo and non-inferiority to Ciprofloxacin for the primary endpoint (time to last unformed stool).

**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 colon cancer. 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*. On

November 16 2018 the FDA has also approved Aemcolo, Cosmo's first oral 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 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

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| Full-year results 2018 reporting | March 2019 |
| Annual General Meeting | May 2019 |

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