Cosmo Pharmaceuticals:
FDA Allowance of IND application for CB-03-10

Dublin – May 7, 2019 – Cosmo Pharmaceuticals NV (SIX: COPN) announced today that the U.S. Food and Drug Administration (FDA) has allowed the Investigational New Drug (IND) application for its new chemical entity CB-03-10 with androgen receptor (AR) and glucocorticoid (GR) receptor antagonist properties, so that it can initiate a phase I clinical trial in tumor bearing patients to evaluate safety, pharmacokinetics and pharmacodynamic activity.

These receptors are expressed in several solid epithelial tumors including pancreas, colon and prostate. The preclinical data are very encouraging as they highlight the potential cooperative nature of AR and GR signaling and justify the clinical exploration of simultaneous AR/GR modulation in cancer. The IND plans to begin enrolling patients in the first human clinical trial by end of the year. The trial is designed to provide data on the product safety and early activity signals.

“Despite significant progresses in cancer treatment over the last few years, there are still several solid tumors for which there is an intense interest in finding new effective medications. Among those are pancreatic cancer, and certain subtypes of prostate cancer that share a poor prognosis and a high unmet therapeutic need. Clinical trials testing new, orally administered, compounds that showed promising activity in pre-clinical models and are directed against well-defined biologic targets could play a key role in improving treatment and survival of patients affected by such cancers” said Prof. Michele Maio, Director of the Center for Immuno-Oncology at the University Hospital of Siena, Italy.

“Cosmo has gathered a significant expertise with anti-androgen compounds over the years, which has translated so far in the development of the two candidate drugs for the treatment of acne (Winlevi) and androgenetic alopecia (Breezula) by Cassiopea. In this context, CB-03-10 has been extensively studied in pre-clinical settings and animal models and we believe it is a very promising compound with exceptional qualities, which we intend to partner after having completed the phase I trial” said Alessandro Della Chà, CEO of Cosmo Pharmaceuticals.

About CB-03-10
CB-03-10 (cortexolone 17α-valerate-21-propionate) is a steroidal NCE cortexolone derivative synthesized by Cosmo Pharmaceuticals. It has shown to be able to provide a tumor growth suppression through the induction of both extrinsic and intrinsic apoptotic pathways via inhibition of the AR and GR. CB-03-10 induces cell death in various tumor cell lines grown in vitro and shows a marked inhibition of tumor growth in experimental animal models of cancer at well-tolerated dose levels. AR and GR receptors are expressed in several solid epithelial tumors including pancreas, colon, prostate, breast, and ovarian carcinomas. GR inhibition may also potentially increase

sensitivity to chemotherapy in cancer therapy and could compensate the lack of activity after some time of exposure recorded for other cell receptors.

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 developed Eleview™, a medical device for polyp excision and is developing Methylene Blue MMX®, a product for the detection of colon cancer, has licensed a novel sedation agent Remimazolam for the territory of the US from Paion 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 and Aemcolo™ which is licensed to Dr. Falk Pharma in Europe. 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

R&D Day, Zurich	May 8, 2019
Shareholders meeting, Amsterdam	May 28, 2019
Jefferies Global Health Care Conference	June 4-6, 2019

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