



Cosmo announces successful outcome of phase III clinical trial for LuMeBlue™

Dublin – November 10, 2016 – Cosmo Pharmaceuticals N.V. (SIX: COPN) announced that its phase III pivotal clinical trial of LuMeBlue™ for the detection of adenomas during colonoscopy has successfully met the primary endpoint. The trial completes the data set necessary for the registration of the product both in the US and EU.

The aim of the colonoscopy is to detect adenomas. Not all adenomas turn into cancers, but all cancers were previously adenomas. Therefore, the effectiveness of the colonoscopy depends on the adenoma detection rate. Ultimately, the more adenomas are detected and extracted, the less cancers will subsequently develop. The aim of LuMeBlue™ is to increase the adenoma detection rate versus the white-light high-definition colonoscopy, the current highest standard of care.

LuMeBlue™ is a tablet containing Methylene Blue, a vital dye. 8 tablets are ingested during the colon preparation procedure. LuMeBlue™ stains the entire colon with the dye. The dye penetrates the mucosal cells in such a way that significantly enhances the detection of adenomas by the endoscopist.

The phase III clinical study with LuMeBlue™ was run by Cosmo in 19 top sites in North America and Europe. It enrolled more than 1,200 subjects in an international multi-centre, randomized, double-blind pivotal trial.

A detailed analysis of the data will be presented at Cosmo's R&D day on November 29, 2016 in Zurich.

Upon its approval, Cosmo will market LuMeBlue™ directly in the USA and intends to establish selective partnerships for the marketing of the product in the Rest of the World.

Alessandro Della Chà, CEO of Cosmo, commented: "This is a fantastic breakthrough for us. LuMeBlue™ is a tipping point for Cosmo because it addresses a major need in a mass market. Colonoscopies are the only way to detect adenomas and therefore prevent colon cancer, the third cause of death within cancer. LuMeBlue™ has proven to substantially increase the adenoma detection rate and therefore provides a major contribution in colon cancer prevention; and even more so if one considers that the trial was not against a placebo, but against the highest current standard of care. The successful trial positions Cosmo uniquely as a lead player in both endoscopy and GI and we look forward to the exploitation of our pipeline for the benefit of our shareholders".

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 a medical device for polyp and adenoma excision and is has completed clinical trials of LuMeBlue™, a diagnostic for the detection of colon cancer as well as new chemical entities that are being developed by the associate company Cassiopea S.p.A. for the topical treatment of skin diseases. Cosmo's MMX® products that have reached 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®. 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

Next events

Jefferies Global Healthcare Conference	November 16, 2016 in London
Credit Suisse Mid Cap Conference	November 17-18, 2016 in Zurich
R&D Day	November 29, 2016 in Zurich
Full-year results 2016 reporting	March 2017
Annual General Meeting	April 2017

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