Cosmo announces details of the successful phase III clinical trials of LuMeBlue™ which will be presented at its R&D day today

Dublin – November 29, 2016 – Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced the details of its successful phase III clinical trial of LuMeBlue™ which will be presented and discussed at its R&D day in Zurich today.

LuMeBlue™ Results

In the trial LuMeBlue™ was compared to Standard of Care ("HDWL": White Light colonoscopy with High Definition endoscopes). The primary endpoint in the phase III trial was the number of subjects with at least one histologically proven adenoma or carcinoma.

LuMeBlue™ attained the primary endpoint identifying 17.71% more patients with adenomas or carcinomas than HDWL (p value 0.009; Relative Risk-RR-1.177). Adenomas were found in 56.3% of all subjects when using LuMeBlue™, whereas HDWL found adenomas in 47.8% of all subjects. LumeBlue™ therefore proves very efficient in flagging lesions.

In the phase III clinical trial the false positive rate (an important secondary endpoint) in the LuMeBlue™ arm was lower than in the HDWL. In the LuMeBlue™ arm 356 subjects out of 485 subjects had an excision. 83 of these subjects (23.3%) were false positives. In the WLHD arm 326 out of 479 subjects had an excision and 97 of these subjects (29.7%) were false positives. Thus LuMeBlue™ finds more subject with lesions than HDWL which subsequently prove to be more adenomas or carcinomas.

LuMeBlue™ was also statistically superior and clinically very meaningful in the segment of subjects with 0-3 excisions, where 75%-80% of the patients are. In the segment of 0-3 excisions covering 362 subjects, the LuMeBlue™ Adenoma detection rate was 45.3%, while the adenoma detection rate covering 376 subjects using WLHD was 35.9% (p value 0.0107). This is an improvement of 26.2% (RR 1.262).

There were no reported major drug related adverse events.

LuMeBlue™ trial design

The LuMeBlue™ trial was conducted in 18 leading centers in 8 countries in North America and Europe. The Intention to Treat Population (ITT) was 1249 subjects, the Full Analysis Set (FAS) was 1205 subjects, the Per Protocol Set (PP) was 1137 subjects and the safety set was 1208 subjects. As agreed with the Regulatory Agencies, the endpoints were set according to FAS.

Four Clinical Research Organisations (CROs) were used: One CRO was responsible for the monitoring activities, one for the electronic CRFs, one for the bio-statistical activities and one for the high definition video recording activities and storing.

Two central histolabs, one each in the EU and one in the USA were responsible for the histologic analysis of the excised tissues, 5 endoscopy centers, 2 in North America and 3 in Europe, were randomly assigned videos for review, and there was one endoscopy charter and one histology charter.

Subject population
In the FAS 479 subjects were treated in the WLHD arm of which 61.6% were males; 47,8% were first-time screening colonoscopies, 6,3% were surveillance colonoscopies performed less than two years since the last colonoscopy and 45,9% were surveillance colonoscopies performed after more than 2 years following the first time colonoscopy.

485 subjects were in the LuMeBlue™ arm of which 60.6% were males, 48% were first time screening colonoscopies, 5.8% were surveillance colonoscopies performed less than two years since the last colonoscopy and 46.2% were surveillance colonoscopies performed after more than 2 years following the first-time colonoscopy.

241 subjects were treated in the confounding arm (not statistically powered).

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.

Mauro Ajani, Chairman of Cosmo, commented: “I am proud of Cosmo having been able to achieve such a result in the field of colon cancer prevention, after several years of hard teamwork. The capacity for flagging lesions is quintessential for making colonoscopies more effective”.

Alessandro Della Chà, CEO of Cosmo, commented: “These results are positive beyond our expectations. We will now prepare the New Drug Application and look forward to a quick and successful review process given that we have a Special Protocol Assessment (SPA) with the FDA. We are very positive about the future of LuMeBlue™ and believe that the product will radically change the field of colonoscopies and save lives. These results position 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.”

R&D day video
As of November 30, 2016, 2.00pm CET, a video of the R&D day will be accessible via the Cosmo website http://www.cosmopharma.com/investor-relations

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 drug 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

Full-year results 2016 reporting	March 24, 2017
Annual General Meeting	April 2017

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