Cosmo announces details of the successful phase III clinical trial of Zemcolo in Travellers' Diarrhoea, 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 its new antibiotic Zemcolo, which will be presented and discussed at its R&D day in Zurich today.

Zemcolo

Zemcolo is an antibiotic belonging to the Ansamycin family, whose Active Pharmaceutical Ingredient is Rifamycin SV, a New Chemical Entity (NCE) in the US. Rifamycin SV is known to be an antibiotic with negligible systemic availability when taken orally. Thanks to Cosmo's proprietary delivery technology, Zemcolo is delivered topically only in the colonic districts. This ensures maximum local deployment of its efficacy for the treatment of colonic infections and avoids earlier delivery in the upper gastrointestinal districts with unnecessary destruction of their beneficial saprophytic flora.

Zemcolo Results

Zemcolo underwent two pivotal trials, with different designs. The first one, performed by Santarus, showed Zemcolo's superiority vs. placebo (p-value= 0.0008). The second one, whose successful outcome was communicated in June, performed by Dr. Falk Pharma, showed Zemcolo's non inferiority vs. Ciprofloxacin (=Cipro, the current standard of care in Travellers' Diarrhoea).

Zemcolo attained the primary endpoint also in this second trial with a Hazard Ratio ≤ 0.764 and a p-value= 0.0018. The Clinical Cure Rate (percentage of patients showing clinical symptoms remission) of Zemcolo was 85.0% vs. 84.8% Cipro.

Zemcolo has shown a very good efficacy in eradicating the whole *E.coli* bacteria family (65.9% vs. 63.7% Cipro) and a very similar failure rate to Cipro (14.8 vs. 15.2 Cipro).

The main parameter to show efficacy in Travellers' Diarrhoea is TLUS (Time to Last Unformed Stools). Zemcolo's TLUS in the patients that completed treatment according to protocol was equivalent to Cipro, 33.3 hrs vs. 32.8 hrs.

In terms of Microbiological Cure Rate, in the patients that had a least one isolated microorganism, the efficacy was also equivalent to Cipro, 49.24% vs. 49.60%.

Zemcolo has been administered in more than 600 patients in phase III only and was optimally tolerated, with only 5.5% of adverse events possibly drug-related.

Upon its approval, Cosmo will market Zemcolo directly in the USA, whereas in Europe and some selected Rest-of-the-World countries Zemcolo will be marketed by Cosmo's licensee Dr. Falk Pharma.

Alessandro Della Chà, CEO of Cosmo, commented: "These results are very good. The New Drug Application drafting is well under way and we will file soon. Zemcolo has excellent anti-infective properties and its unique delivery mechanism positions us ideally for further quick exploitation in other key areas of gastrointestinal diseases such as Inflammatory Bowel Disease and Diverticulitis. Zemcolo will also enjoy, once approved, a doubling of regulatory exclusivity under the joint NCE-GAIN rules. Furthermore its main competitor, Cipro, has just received a FDA black-box warning limiting its use to severe infections. For all these reasons, Zemcolo has a great edge over its competitors. I am strongly convinced that the potential of Zemcolo in our pipeline has been seriously underestimated and that it has, by itself, the capacity of significantly changing our landscape".

R&D day video

As of November 30, 2016, 2.00 pm CET, a video of the R&D day will be accessible via 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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