Cosmo announces successful outcome of Rifamycin 600mg Phase II trial in IBS-D

Dublin, Ireland – 11 January 2021: Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced the successful outcome of its Phase II Proof of Concept (POC) clinical trial of Rifamycin-MMX 600mg in Irritable Bowel Syndrome with Diarrhea (IBS-D).

The drug tested is different from Aemcolo®/Relafalk®, which is already approved for Traveler's Diarrhea: while it shares the same active ingredient (Rifamycin SV) and MMX technology, it contains a higher dose of API (600mg) and different release features.

The trial investigated the efficacy and safety of two doses of Rifamycin SV-MMX 600mg against placebo after a 2-week course of treatment followed by a 3 months follow-up. The primary endpoint was the proportion of subjects who achieved success, defined as an adequate relief of both abdominal pain and diarrhea at the end of the first week of treatment (at least 30% decrease in pain score and at least 50% reduction in the number of days per week with diarrhea). Other endpoints included reduction in bloating, improved stool consistency, decreased sense of urgency, and improvement in quality of life as assessed through the IBS QoL questionnaire. The trial was conducted in 25 sites located in 4 countries in Western Europe and recruited 279 patients in the ITT ("Intention to treat") population.

The trial was very successful notwithstanding the decision by Cosmo to reduce the envisaged sample size by 20% due to COVID-19 restrictions. Results show the achievement of statistical significance in all the study populations (ITT, FAS, m-FAS and PP) for the composite primary endpoint (substantial pain and diarrhea decrease) [OR 3.26 (1.39 – 7.67); p-value 0.0066] and for most secondary endpoints such as adequate relief of IBS-related symptoms [OR 2.18 (1.12 – 4.26); p-value 0.0227] and IBS-related bloating at the end of treatment period [OR 2.13 (1.11 – 4.07); p-value 0.0223].

Cosmo, together with its licensees, will immediately commence discussions with the US and EU regulatory agencies with a view to starting the Phase III clinical studies required for marketing authorisation as soon as possible.

Alessandro Della Chà, CEO of Cosmo, said: "*The successful outcome of the Rifamycin SV MMX 600mg phase II trial in IBS-D was a long sought milestone. These results grant the prosecution of the development path with very encouraging data. We are looking forward to continuing the advancement of our drug candidate towards much larger markets such as the IBS-D*".

Stefano Selva, CSO of Cosmo, said: "*These results confirm the capacity of our product Rifamycin SV MMX to perform very well as an anti-inflammatory agent, in addition to the already well-known anti-infective properties*".

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders and improve endoscopy quality measures through aiding the detection of colonic lesions. Cosmo has also developed medical devices for endoscopy and has recently entered into a partnership with Medtronic for the global distribution of GI Genius™ its artificial intelligence device for use in coloscopies and GI procedures. Cosmo has licensed Aemcolo® to Red Hill Biopharma Ltd. for the US and has licensed Relafalk® to Dr. Falk Gmbh for the EU and other countries. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Calendar

Full Year Results 2020	March 26, 2021
Annual General Meeting, Amsterdam	May 28, 2021

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