Methylene Blue MMX approved in Europe for the visualization of colorectal lesions during colonoscopies – first oral drug ever approved in the world to improve the outcome of colonoscopies

Dublin, Ireland - 21 August 2020: Cosmo Pharmaceuticals NV (SIX: COPN) today announced that the European Commission (EC) has approved Methylthioninium Chloride Cosmo, prolonged release tablets (Methylene Blue MMX) for the visualization of colorectal lesions during colonoscopies. This is the first approval of Methylene Blue MMX and is also the first time an oral drug has been approved to improve the outcome of colonoscopies. The Centralized European licence will be effective simultaneously in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

Mauro Ajani, Chairman of Cosmo, said: *"This approval is wonderful news. Cosmo is finally providing the first oral drug ever approved to help prevent colorectal cancer by improving the quality of the colonoscopy procedure."*

Alessandro Della Chà, CEO of Cosmo, said: *"We are very pleased with the news and we were always convinced that the very good clinical data should have granted approval. Now MB MMX can start to help patients undergoing colonoscopies by improving Adenoma Detection Rate and preventing the miss of many lesions".*

The approval was based on CHMP prior positive opinion based on the data stemming from the single phase III trial performed by Cosmo worldwide in 20 sites involving 1,249 randomised patients. The study was powered to show a statistically significant difference between Methylene blue MMX 200 mg and placebo (corresponding to High-Definition White Light [HDWL] colonoscopy – the current standard of care) in the detection of patients with at least one adenoma or carcinoma (Adenoma Detection Rate [ADR]). The study met its prespecified endpoint: the ADR was higher in the Methylene Blue MMX arm as compared to HDWL colonoscopy (56.29% vs 47.81%, respectively; difference: 8.48%; RRI 17.7%; OR [95% CI]: 1.41 [1.09, 1.81]; p-value: 0.0099).

Important prespecified secondary endpoints showed that Methylene Blue MMX increases the detection of patients with at least one adenoma and does not produce an increase in the False Positive Rate (FPR) as compared to HDWL colonoscopy. Additional endpoints showed that Methylene Blue MMX increases, in particular, detection of non-polypoid (flat) lesions (the most frequently missed lesions).

The indication of Methylene Blue MMX recommended for approval by the CHMP is as a *"diagnostic agent enhancing visualization of colorectal lesions in adult patients undergoing screening or surveillance colonoscopy".*

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 and is the licensee of BYFAVO™ (Remimazolam) for the US for procedural sedation, which it has sub-licensed to Acacia. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Financial calendar

Investora, Zurich September 23, 2020

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