Cosmo receives positive EMA CHMP Opinion recommending approval of Methylene Blue MMX for the visualization of colorectal lesions during colonoscopies

Dublin, Ireland - June 26, 2020. Cosmo Pharmaceuticals NV (SIX: COPN) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Methilthioninium Chloride Cosmo (Methylene Blue MMX), its drug for the visualization of colorectal lesions during colonoscopies.

The CHMP recommendation will now be reviewed by the European Commission, which has the authority to approve medicines centrally for the European Union. Access to the centralised procedure had been granted to Methylene Blue MMX on the grounds of its significant innovation and interest for patients. The final decision on the Marketing Authorisation Application for Methylene Blue MMX is expected in the next couple of months. The granting of a centralised 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.

Alessandro Della Chà, CEO of Cosmo, said: "*This positive CHMP opinion is great news for Cosmo. It confirms that Methylene Blue MMX has the potential to become an important aid during colonoscopies for the visualization of those 'easy to miss' lesions and to enhance the overall performance of endoscopists by increasing their Adenoma Detection Rate.*"

Mauro Ajani, Chairman of Cosmo, said: *"The positive recommendation for Methylene Blue MMX by the EMA is a very significant achievement for Cosmo and a great advancement in the fight against colorectal cancer. I wish to thank all those that helped Cosmo get to this point."*

The CHMP adopted the positive opinion based on the data stemming from the single phase III trial performed by Cosmo worldwide in 20 sites involving 1249 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).

Based on the benefits of Methylene Blue MMX in terms of increase in ADR and on the lack of major safety issues, the CHMP adopted a positive benefit/risk balance.

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 U.S. 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

2020 Half-Year Results July 30, 2020

Contact

Niall Donnelly, CFO & Head of Investor Relations
Cosmo Pharmaceuticals N.V.
Tel: +353 1 817 03 70
ndonnelly@cosmopharma.com