Cosmo Pharmaceuticals Methylene Blue MMX regulatory update: filing of protocol for confirmatory phase III trial for Methylene Blue

Dublin, Ireland – April 2, 2020 - Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced that it has filed for final comment the protocol and related statistical analysis plan with the U.S. FDA for the confirmatory phase III trial for Methylene Blue MMX, an investigational new drug product developed as an aid for the detection of colorectal lesions in patients undergoing routine screening and surveillance of colonoscopies.

The FDA has agreed to expedite review of the protocol upon receipt and to provide feedback within a 30 to 60 day timeframes. Notwithstanding the main elements have already been previously aligned with the agency, it is possible that this deadline will be impacted by the pandemic disruptions. Cosmo plans to commence the confirmatory phase III trial in H2, subject to acceptance of the protocol by the FDA and subject to normal clinical operations resuming to ordinary standards.

Cosmo will provide further updates on the process and remains fully committed to bringing this potential improvement to existing standards of care for colonoscopy screening and surveillance to the health care system as soon as possible. Effective screening and surveillance are critical to the prevention of colorectal cancer and the reduction in the overall incidence of life-threatening colorectal cancer.

About Cosmo Pharmaceuticals
Cosmo is a specialty pharmaceutical company focused in treating selected Gastrointestinal Disorders and Endoscopy. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, Colonic Infections and 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 its novel Artificial Intelligence device to be used in coloscopies and GI procedures. Further, Cosmo has licensed Aemcolo™ to Red Hill Biopharma and is the licensee for U.S. of the novel agent for procedural sedation, remimazolam, which it has sub-licensed to Acacia. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Calendar

Full Year Results 2019	April 3, 2020
Annual General Meeting	May 28, 2020

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