



Cosmo's oral diagnostic drug Lumeblue[®] receives approval of New Drug Application in China

Dublin, Ireland – 18 June 2024: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") reported that its partner and exclusive licensee of Lumeblue[®] (Methylene Blue MMX[®]) for China, China Medical System Holdings Limited ("CMS") (SEHK: 867), has received the approval for the innovative product in the territory by the National Medical Products Administration of China (NMPA) on 11 June. Today, on 18 June, CMS also obtained the corresponding Drug Registration Certificate. Cosmo will be the exclusive supplier for the product.

According to diagnosis and treatment data of the Digestive Endoscopy Branch of the Chinese Medical Association, approximately a total of 28 million gastroenteroscopies were completed nationwide in 2012, including 5.83 million colonoscopies. In 2019, approximately 38.73 million gastroenteroscopies were completed nationwide, an increase of 34.62% compared with 2012.¹ The "Chinese Consensus of Early Colorectal Cancer Screening" recommends that people aged 50 to 75 years old should be screened for colorectal cancer regardless of whether they have alarm symptoms.² There were approximately 400 million people aged 50 to 75 in China in 2020.³ With the popularity of early screening for colorectal cancer in China, it is expected to witness a considerable growth of the number of colonoscopies in China in the future.

The results of the phase III clinical trial conducted in China were published in December 2022 and demonstrated that Lumeblue[®] can significantly improve the detection rate of non-polypoid colorectal lesions (the primary endpoint of the study), leading to an improved detection rate of dangerous lesions such as non-polypoid adenomas (the secondary endpoint).⁴ In addition, Lumeblue[®] can be taken during the bowel preparation step, ensuring that colorectal staining is completed by the time colonoscopy is conducted. This not only enhances the detection rate of colorectal lesions but also potentially simplifies the colonoscopy procedure, making the examination more efficient and improving the screening benefits.

Giovanni Di Napoli, CEO of Cosmo, said: *"We are extremely proud of this significant advancement in our pipeline. The Chinese market presents immense potential for Lumeblue[®], and with CMS as our partner, we are perfectly positioned to capitalize on this opportunity."*

About Lumeblue[®]

Lumeblue[®] (Methylene Blue MMX[®]) is oral diagnostic drug that uses Cosmo's own patented proprietary Multi-Matrix (MMX) technology. It delivers the active substance directly to the colon and release it locally in a controlled manner, allowing for staining of the colonic mucosa. As an enhancer dye, Lumeblue[®] increases the contrast between colorectal lesions and healthy mucosa. The drug was approved in Europe in August 2020. In December 2020, Cosmo licensed the rights for Greater China including mainland China, Hong Kong, Macao, and Taiwan to CMS; in March 2023, Cosmo and CMS signed a territory expansion agreement which expand the CMS territories to more than 25 additional countries in the "Pan-Asian" region.

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda[®]/Mezavant[®]/Mesavancol[®],

¹ The diagnosis and treatment data of the Digestive Endoscopy Branch of the Chinese Medical Association.

² Chinese Consensus of Early Colorectal Cancer Screening (2019, Shanghai), Chinese Journal of Internal Medicine, DOI: 10.3760/cma.j.issn.0578-1426.2019.10.004.

³ CHINA POPULATION CENSUS YEARBOOK 2020, see www.stats.gov.cn/sj/pcsj/rkpc/7rp/zk/indexch.htm.

⁴ See web.cms.net.cn/en/2022/12/positive-results-for-china-phase-iii-clinical-trial-of-methylthioninium-chloride-enteric-coated-sustained-release-tablets/.



Uceris®/Cortiment®, Aemcolo®/ Relafalk®, Lumeblue® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. The company also has a rich development pipeline. For additional information on Cosmo and its products, please visit www.cosmopharma.com.

About CMS

CMS is a platform company linking pharmaceutical innovation and commercialization with strong product lifecycle management capability, dedicated to providing competitive products and services to meet unmet medical needs. CMS focuses on the global first-in-class (FIC) and best-in-class (BIC) innovative products, and efficiently promotes the clinical research, development and commercialization of innovative products, enabling the continuous transformation of scientific research into clinical practices to benefit patients. CMS deeply engages in several specialty therapeutic fields, including cardio-cerebrovascular, gastrointestinal, central nervous system, dermatology, ophthalmology and pediatrics etc., and it has developed proven commercialization capabilities, extensive networks and expert resources, resulting in leading academic and market positions for its major marketed products. For additional information on CMS and its products, please visit www.cms.net.cn.

Upcoming Calendar of Events

Extraordinary General Meeting	July 5, 2024
Half Year Results 2024	July 24, 2024

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