



Cosmo announces territory expansion agreement for Lumebblue™ (Methylene Blue MMX™) with China Medical System Holdings

Dublin, Ireland – March 30, 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) today announced the territory expansion of the license agreement for Lumebblue™ with China Medical System Holdings Limited (“CMS”) (SEHK: 867). The expansion goes beyond the existing licensed territories (Greater China including the mainland China, Hong Kong, Macao, and Taiwan) to include several countries belonging to the “Pan-Asia” region. These include several countries belonging to Central, Eastern, Southeastern and Southern Asia which are outlined below:

Central Asia	Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan
Eastern Asia	Republic of Korea, Mongolia
Southeastern Asia	Brunei Darussalam, Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand, Timor-Leste, Vietnam
Southern Asia	Afghanistan, Bangladesh, Bhutan, Iran (Islamic Republic of), Maldives, Nepal, Pakistan, Sri Lanka

This territory expansion is following the successful results reported from the phase III clinical trial of Lumebblue™ in China. Cosmo will continue to be the exclusive supplier of Lumebblue™ also for these regions.

Reported successful phase III clinical trial of Lumebblue™ in China:

In December 2022, Cosmo announced the successful phase III clinical trial of Lumebblue™ in China, sponsored by its partner China Medical System Holdings Limited (CMS) (867.HK). The study was a randomized, double-blind, placebo-controlled trial (placebo being in this case the standard of care) run under GCP in 22 sites across China.

The study met the primary endpoint with very high statistical significance. Please refer to full details in the press release published [here](#).

CMS has filed the NDA in December 2022 and has received confirmation of the acceptance of filing in Q1 2023.

Alessandro Della Chà, CEO of Cosmo Pharma, said: “*We are pleased to expand and strengthen this partnership further with CMS with the aim to make Lumebblue™ available to more patients around the world. Colorectal cancer is one of the most common malignant tumour in the digestive system, with a high incidence, high mortality and poor progress throughout the world. We are thus very much looking forward to working together with CMS to bring Lumebblue™ in these regions*”.

About Lumebblue™ (Methylene Blue MMX™, EMA-approved prescription drug)

Lumebblue® is an oral diagnostic drug. The tablet is a locally released vital dye formulation using Cosmo’s own patented proprietary Multi-Matrix (MMX) technology that allows the delivery of the active ingredient directly into the colon; the tablet structure allows for the controlled release of the dye throughout the entire colon. The methylene blue dye acts as



contrast enhancer, increasing the contrast between colorectal lesions and healthy mucosa. This allows endoscopists for a better visualization and detection of the colorectal lesions. This in turn translate into the clinical benefit of an increased detection of dangerous neoplastic lesions like adenomas or colorectal cancers.

The drug was approved in Europe on 21 August 2020, following a successful global Phase III trial. In February 2021 Cosmo licensed the E.U. rights (plus Switzerland, the U.K., E.E.A. countries and Mexico) to Alfasigma S.p.A.

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercializing 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®, Uceris®/Cortiment®, Aemcolo®/ Relafalk® 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 the Company's website: www.cosmopharma.com

Upcoming Calendar of Events

Annual General Meeting 2023	May 26, 2023
Half Year Results 2023	July 27, 2023

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