



Cosmo announces FDA approval of GI Genius™ intelligent endoscopy module, its revolutionary Artificial Intelligence device for lesion detection during colonoscopy

Dublin, Ireland – 12 April 2021: Cosmo Pharmaceuticals NV (SIX: COPN) today announced the FDA approval of GI Genius™ intelligent endoscopy system, its revolutionary device for lesion detection during colonoscopy.

The GI Genius module FDA approval marks a pivotal milestone for Cosmo after more than 10 years of research and investments focused to generate disruptive innovations in the field of colon's disease and optimization of the colonoscopy procedure. The development of GI Genius intelligent endoscopy module has been possible thanks to the leadership position of Cosmo, its unique proprietary library of high-definition loss-less videos of colonoscopies and its proprietary software and algorithms. The device is the first of its kind to obtain the FDA approval through the De Novo application. The device operates in real time to assist the endoscopist in the detection of lesions, is very simple to use and is compatible with all endoscopes. Cosmo is the sole manufacturer. Medtronic is the exclusive world-wide distributor.

According to Prof. Michael Wallace, Fred C. Andersen Professor of Medicine at Mayo Clinic and Editor in Chief of Gastrointestinal Endoscopy: *“While colon cancer is the second deadliest cancer worldwide, it is the most preventable cancer yet full prevention remains unfulfilled. 1 in 20 US adult will be diagnosed with this disease in their lifetime but, encouragingly, 90% of patients can beat it if it is diagnosed early enough. Colonoscopy is the gold standard and most common screening method, but it’s not perfect, as performance varies based on many factors including physician skill level. The GI Genius intelligent endoscopy module will help improve the accuracy of colonoscopy and reduce the number of undetected precancerous lesions, as has been shown in a recent randomized study (Repici et al.), where detection rates improved very significantly with GI Genius technology versus standard colonoscopy, regardless of skill level or endoscope used”.*

Mauro Ajani, Chairman of Cosmo, commented: *“this landmark approval is tremendous news for Cosmo. The first ever approval of an artificial intelligence device for lesion detection in colonoscopies further strengthens Cosmo’s commitment to fight colorectal cancer. This approval is a major milestone after many years of strategic investments into the colon diseases and positions Cosmo at the forefront of cutting-edge innovation. Through the strong partnership with Medtronic over the last two years, Cosmo has expanded its position in the medical device market within its core GI expertise, has gained global access and will ultimately reach more patients. We are extremely pleased and very optimistic about the impact the GI Genius intelligent endoscopy module will have on the US patient population undergoing colonoscopy”.*

Alessandro Della Chà, CEO of Cosmo, said: *“This approval is gratifying in many ways as it is aligned with our mission of serving markets with unmet needs. Through our global distribution partnership with Medtronic we are excited to pursue an opportunity which is worth at least \$ 1.1bn, looking only at the opportunity for artificial intelligence in the*

colonoscopy market. Leveraging on the strength of Medtronic's large US commercial footprint, we look forward to successfully and rapidly developing this market".

The GI Genius™ intelligent endoscopy system is a registered trademark of Medtronic plc.

The FDA announcement of the approval can be found at the following link: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-device-uses-artificial-intelligence-help-detect-potential-signs-colon>

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 Ltd. for the US and has licensed Relafalk® to Dr. Falk GmbH for the EU and other countries. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Calendar

Annual General Meeting, Amsterdam	May 28, 2021
Half-Year 2021 Report	July 30, 2021

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