DETECT study shows AI assistance using GI Genius™ reduces missed polyp rate by nearly 50% on initial colonoscopy

Dublin, Ireland – November 19, 2021: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") today announced topline results from a randomized, international, multi-center study evaluating the safety and efficacy of artificial intelligence (AI) device GI Genius™ as an aid for the detection of colorectal polyps in combination with colonoscopy. The DETECT study was designed to provide evidence of the advantages of using GI Genius™ in the real-time detection of colorectal polyps and to assess if the use of GI Genius™ would decrease the miss rates of colorectal polyps and adenomas when compared to white light endoscopy.

The topline results show that both the primary and the secondary endpoint of the study were met with very high statistical significance: the adenoma miss rate (AMR) was significantly lower when GI Genius™ was used in the first colonoscopy as compared to when white light endoscopy was used in the first colonoscopy (15.5% vs 32.4%; p-value <0.001). The polyp miss rate (PMR) was significantly lower when GI Genius™ was used in the first colonoscopy as compared to when white light endoscopy was used in the first colonoscopy (16.9% vs 31.1%; p-value <0.001). These findings demonstrate that the use of GI Genius™ significantly decreases the miss rate of both adenomas and polyps, further confirming the enhancements GI Genius™ adds to colonoscopy procedures.

"This study provides a wide experience of the use of the device in clinical settings, and the results show how effective GI Genius™ is in reducing the percentage of adenomas and polyps that go undetected during white light colonoscopy," said Prof. Michael B. Wallace, M.D., M.P.H., Chief, Division of Gastroenterology and Hepatology, Sheikh Shakhbout Medical City. *"Previous studies estimate that 50-60% of interval cancers arise from lesions not seen at the index colonoscopy, and this study shows clear evidence GI Genius™ prevents such misses – cutting the miss rates of both adenomas and polyps in half,"* said Dr. Wallace.

The primary endpoint of the study was the adenoma miss rate (AMR), representing the percentage of adenomas or carcinomas that were found at the second colonoscopy and were therefore undetected at the first colonoscopy. The secondary endpoint of the study was the polyp miss rate (PMR), representing the percentage of polyps that were found at the second colonoscopy and were therefore undetected at the first colonoscopy. The objective of the study was to assess if the AMR and PMR were lower when GI Genius™ was used in the first colonoscopy, as compared to when white light endoscopy was used in the first colonoscopy.

"We were extremely pleased with these new findings that demonstrate GI Genius™ can help physicians more accurately detect polyps and adenomas," said Giovanni Di Napoli, president of the Gastrointestinal business at Medtronic, the exclusive worldwide distributor of the GI Genius™ module. *"As the second deadliest cancer in the world, early diagnosis expands treatment options and is critical to saving lives. GI Genius™ increases colorectal polyp detection, which reduces the risk of interval cancers that can occur between colonoscopies – enabling better care for patients."*

"We know from tandem studies that the gold-standard white light endoscopy is far from being perfect, and that several lesions can go undetected during a colonoscopy," said Alessandro Della Chà, CEO of Cosmo Pharmaceuticals. *"As a company, we are extremely proud to have developed an AI tool that we believe will become the standard of care in the fight against colorectal cancer."*

The DETECT study (clinicialtrials.gov identification number: NCT03954548) was conducted in the US and Europe (Italy and United Kingdom). Conducted in university hospitals and community clinics, study subject included male and female patients aged 45 or older undergoing a screening or surveillance colonoscopy for colorectal cancer. In total, 249 subjects were randomized in the study, of whom 229 subjects completed the study and were included in the primary efficacy analysis, undergoing two consecutive colonoscopies that were randomly assigned in order of which they were conducted: one with GI Genius™ and a colonoscopy with white light endoscopy.

GI Genius™ is authorized in the US and approved in Europe; however, indications may differ. Be sure to consult your IFU for the cleared or approved GI Genius™ indications for your region.

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 a partnership with Medtronic for the global distribution of GI Genius™ its artificial intelligence device that uses artificial intelligence to help detect potential signs of colon cancer. 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

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