



## PRESS RELEASE

# Italian pharmaceutical company Alfasigma launches diagnostic drug Lumebblue™ ahead of World Digestive Health on 29 May

- ***WDHD 2022 is dedicated to raising awareness on colorectal cancer prevention***
- ***In Europe more than 519,820 new cases of colorectal cancer (CRC) were diagnosed in 2020***
- ***Adenoma detection rate (ADR) is crucial in the prevention of CRC***
- ***Lumebblue™ outcomes from a phase III study showed increases in the absolute ADR rate of 8.5%***

**Bologna, Italy**

May 25, 2022

Ahead of **World Digestive Health 2022**, Italian pharmaceutical group Alfasigma is proud to announce the launch of its new diagnostic drug Lumebblue™ (per-oral methylene blue). This latest innovation is part of the company's commitment to raising awareness on colorectal cancer (CRC), still the second leading cause of cancer deaths worldwide, through a healthy lifestyle and regular screenings.

Lumebblue™ is approved by EMA (European Medicines Agency) for the detection of lesions during colonoscopy. Lumebblue™ was in a symposium titled "A new tool in colonoscopy: Per-oral methylene blue" at ESGE Days 2022 as a new diagnostic drug to improve the detection of lesions during colonoscopy. In Europe, CRC is the second most common oncological disease in terms of incidence and mortality, with 519,820 new cases and 244,824 deaths registered in 2020.

The symposium was held in the presence of about 400 European physicians from the areas of colonoscopy, gastroenterology, surgery, and internal medicine.

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Main lectures were presented by three of the most influential experts in the field, Michal Kaminski, Prateek Sharma, and Alessandro Repici.

*“Improving the ADR, even from a threshold above 25%, reduces the risk of interval cancer or colon rectal cancer death in both the screened population and high-risk CRC patients,”* affirmed professor **Michal Kaminski**, Head of the Department of Cancer Prevention and Head of Endoscopy Unit in the Department of Gastroenterological Oncology at the Maria-Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland. *“Quality parameters in colonoscopy and the significance of the adenoma detection rate (ADR), which, although shows a high variation among endoscopists in clinical practice, is one of the key performance measures in colonoscopy for the identification of the disease in patients at various levels of risk of Colon Rectal Cancer, and is applicable to all indications of colonoscopy.”*

Chromoendoscopy in screening and surveillance starting from current limitations and unmet needs in standard colonoscopy were the topics lectured by professor **Prateek Sharma**, Section Chief of Gastroenterology at the Kansas City Veterans Affairs Medical Centre and Program Director at the University of Kansas School of Medicine: *“Data from the medical literature show that dye-based chromoendoscopy improves polyp detection and ADR compared to HD white light colonoscopy or virtual chromoendoscopy. However, this technique highlights the increased withdrawal time for colonoscopy, while the oral use of methylene blue in colon preparation can be more promising.”*

In conclusion, professor **Alessandro Repici**, Professor of Gastroenterology at Humanitas University Medical School, introduced his experience with per-oral methylene blue in colonoscopy. He explained how to move out from the cumbersome procedure applied with the dye-spray chromoendoscopy to a new perspective of dye use: *“The adoption of traditional chromoendoscopy in routine colonoscopy has several barriers and is not a real time procedure because of practical issues to prepare and dispense the dye during colonoscopy.”* Repici presented the clinical outcomes from a phase III study showing the use of Lumeblue™ in patients undergoing screening and surveillance endoscopy, increases the absolute ADR rate of 8.5% as a mirroring result of data that can be currently reported in clinical studies using artificial intelligence. *“The use of Lumeblue™ is targeted to colonoscopy in FIT+ patients, high risk (IBD/hereditary nonpolyposis colorectal cancer), screening or surveillance and is totally safe from warnings of genotoxicity of methylene blue,”* Prof. Repici concluded.

Lumeblue™ is now available in Italy, after the commercial launch by Alfasigma held in early April and will be launched in the next months in other European countries.

In fact, in February 2021, Alfasigma reached a licensing agreement with Cosmo Pharmaceuticals NV (SIX: COPN) in the EU rights (plus Switzerland, UK, European Economic Area countries, Russia, and Mexico) for Lumeblue™.

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### About Alfasigma

Privately owned, Alfasigma is an Italy based multinational pharmaceutical company with a presence in over 90 countries through distributors and subsidiaries. The company employs a workforce of around 3,000 people, has in-house R&D capabilities, and several production plants. Alfasigma is known for its strong focus on gastroenterology and vascular.

More information is available at <https://www.alfasigma.com>.

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