

**HILOPROBE**

Personalizing colorectal cancer diagnostics and prognosis

PRESS RELEASE

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Biocartis and HiloProbe to Collaborate on Colorectal Cancer Test

Mechelen, Belgium, 9 May 2023 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), and HiloProbe, a Umeå (Sweden) based biotechnology company focused on personalizing colorectal cancer diagnostics, today announce that they entered into a collaboration that will initially focus on the commercialization of [ColoNode[®]](#), a CE-marked IVD gene expression signature test that can help detect nodal metastasis in colorectal cancer (CRC) patients. ColoNode[®] will be distributed as a manual kit by Biocartis to expert laboratories in selected European countries.

CRC is the third most common cancer type in the world with an estimated 1.9 million new cases and 0.9 million deaths per year worldwide¹. 70-90% of CRC patients may undergo surgical resection of the tumor. International guidelines² have introduced the tumor-node-metastasis (TNM) staging system, that assesses primary tumor (T), lymph node metastasis (N), and distant metastasis (M) to predict disease recurrence and survival. As a key component in this staging system, lymph nodes that are contained in the resected section of the colon, are inspected for presence of disseminated tumor cells. Lymph node status is also a key factor in deciding on post-operative adjuvant chemotherapy. The routine method of determining lymph node status (pN) is microscopic examination of H&E³ stained lymph node tissue sections, that has limitations: it is insensitive and subjective, requires specially trained pathologists, examines < 1% of the lymph node volume and cannot differentiate between aggressive and relatively harmless tumor cells.

ColoNode[®] is a CE-marked IVD gene expression test that detects and characterizes tumor cells in post-operative CRC lymph node samples. The ColoNode[®] kit can analyze up to 100% of the lymph node volume and is more sensitive in detecting tumor cells than H&E staining. Additionally, the test provides an estimation of the risk of CRC recurrence based on the tumor aggressiveness markers included in the ColoNode[®] kit⁴.

The partnership will initially focus on the commercialization of the ColoNode[®] CE-marked IVD manual kit in selected European countries by Biocartis. Following commercial uptake of the manual kit, HiloProbe and Biocartis will consider developing a fully automated version of the test on Biocartis' decentralized Idylla[™] platform.

Roger Moody, Chief Executive Officer of Biocartis, commented: "We are pleased to partner with HiloProbe on the distribution of the ColoNode[®] kit. This allows us to broaden our product offering to customers in the colorectal cancer domain, complementing tests for RAS biomarkers and MSI on our Idylla[™] platform. The collaboration supports our mission to maximize patient access to precision medicine in oncology."

Lina Olsson, Chief Executive Officer of HiloProbe, added: "We are very happy to start a collaboration and a long-term relationship with Biocartis, which strengthens our focus on colorectal cancer thanks to Biocartis' established sales and distribution network across many countries. Further development of a fully automated version of ColoNode[®] on the Idylla[™] platform also holds great potential for ColoNode[®] to contribute faster and more easily to the safer selection of patients who could benefit from postoperative adjuvant treatment."

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1 Globocan 2020 and Xi and Xu. Global colorectal cancer burden in 2020 and projections to 2040. Translational Oncology 14 (2021): 101174

2 American Joint Committee on Cancer (AJCC) and International Union Against Cancer (UICC)

3 H&E (hematoxylin-eosin) stain is the most widely used tissue staining used in histopathology

4 Ohlsson et al. Int J Cancer 2012, 130: 1833; Ohlsson et al. Br J Cancer 2012, 107: 150; Olsson et al, PLoS ONE 2020, 15: e0229007; Olsson et al. Dis Colon Rectum 2021, 64: 1354.

About Biocartis

With its revolutionary and proprietary Idylla™ platform, Biocartis (Euronext Brussels: BCART) aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. Idylla™'s continuously expanding menu of molecular diagnostic tests address key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung, liver and breast cancer, as well as for COVID-19, Flu, RSV and sepsis. For more information, visit www.biocartis.com or follow Biocartis on [Twitter](https://twitter.com/Biocartis_) @Biocartis_ , [Facebook](https://www.facebook.com/Biocartis) or [LinkedIn](https://www.linkedin.com/company/biocartis).

About HiloProbe

HiloProbe is a biotechnology company founded 2016. The founders consist of a group of scientists, who have collaborated for more than 15 years in an academic setting and have produced high quality original research focusing on the development of clinically useful biomarkers in colorectal cancer. The research has been focused on analysis of the regional lymph nodes in the resected specimen. The reason is that the lymph node is the first site where metastasizing cancer cells will occur. We have now discovered a limited number of biomarkers that, when analyzed together, identify tumor cells in the lymph node and grade tumor cell aggressiveness i.e. their propensity to metastasize to distant sites. A product (ColoNode®), based on biomarker mRNA analysis, has been developed. The aim is to bring ColoNode® to the market to save people's lives and aid in the development of more efficient treatment of colorectal cancer.

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