



PRESS RELEASE

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Biocartis launches second liquid biopsy assay

Assay co-developed with Merck for detection of KRAS mutations, operating directly on 1 ml blood plasma

Mechelen, Belgium, 7 December 2016 - Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of its second liquid biopsy assay, the Idylla™ ctKRAS Mutation Assay (Research Use Only, RUO), which was developed in partnership with the leading science and technology company Merck¹ on Biocartis' molecular diagnostics platform Idylla™. Designed to perform easy, sensitive and rapid KRAS mutation testing operating directly on 1 ml of blood plasma, the Idylla™ ctKRAS Mutation Assay (RUO) is the second liquid biopsy assay on the Idylla™ platform, after the ctBRAF Mutation Assay launched end of 2015.

Earlier this year, on 7 January 2016, Biocartis and Merck announced a partnership to jointly develop and commercialize new liquid biopsy RAS biomarker tests for metastatic colorectal cancer (mCRC). Access to rapid and easy-to-use molecular diagnostic tests is essential to understand individual cancer-driving gene mutations in mCRC, opening doors to timely cancer treatment decision-making. Liquid biopsy-based testing demonstrates clear benefits as it, contrary to tumor tissue-based testing, is minimally invasive, fast and easy to perform and an attractive approach when limited or no tissue is available.

The new Idylla™ ctKRAS Mutation Assay (RUO) is a fully automated sample-to-result assay that operates directly on 1 ml of blood plasma. The assay is intended for the qualitative and sensitive detection of 21 KRAS mutations, with less than 1 minute of hands-on time and a turnaround time of approx. 130 minutes.

The newly launched Idylla™ ctKRAS Mutation Assay (RUO) further supports Biocartis' colorectal cancer test offering, today consisting of the tissue-based Idylla™ KRAS Mutation Test (CE-marked IVD test) and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (RUO), both operating directly from a slice of FFPE² tumor tissue. The Biocartis partnership with Merck also comprises the development of a second liquid biopsy test addressing NRAS and BRAF mutations to complete liquid biopsy ctRAS testing coverage in mCRC. The Idylla™ ctNRAS-BRAF Mutation Assay (RUO) is expected in the first quarter of 2017.

Erwin Sablon, Head of R&D and Alliance Management Biocartis, commented: *"Thanks to our partnership with Merck, Biocartis is able to offer its first liquid biopsy assay for KRAS mutation testing, operating directly on blood plasma. We are excited about the potential of this and future liquid biopsy assays, where research³ has shown in the past years that circulating tumor DNA can be used for disease monitoring in patients undergoing treatment."*

Under the partnership with Merck, CE-marked IVD versions of the Idylla™ ctRAS tests are expected to be launched in the second half of 2017. Once these have been validated for diagnostic use, the tests will be implemented in numerous medical centers across the world (excluding the U.S., China and Japan) for which currently discussions are ongoing in several European countries, the Middle-East, Asia-Pacific and Latin-America.

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¹ Merck KGaA.

² Formalin-fixed paraffin embedded.

³ Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.

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About liquid biopsy testing

Research over the last few years has shown that fragments of tumor DNA are shed into the blood from primary tumors or metastatic sites⁴. These circulating DNA fragments can be used for diagnostic purposes, such as providing molecular information for treatment selection, or for monitoring disease progression in patients undergoing treatment. According to J.P. Morgan, the global market of liquid biopsy tests is estimated to reach \$20 billion by 2020.

About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis launched the Idylla™ platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers six oncology tests and two infectious disease tests. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis_.

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⁴ Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.