



PRESS RELEASE

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Biocartis launches CE-marked IVD RAS liquid biopsy tests developed under partnership with Merck KGaA, Darmstadt, Germany

The Idylla™ ctRAS liquid biopsy tests detect RAS mutations in patients with metastatic colorectal cancer

Mechelen, Belgium, 27 November 2017 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of two CE-marked IVD liquid biopsy tests, the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test. The Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test are Biocartis' first CE marked liquid biopsy tests for in vitro diagnostic use in detecting RAS and BRAF mutations in patients with metastatic colorectal cancer (mCRC). Developed under the partnership with the leading science and technology company Merck KGaA, Darmstadt, Germany, the launch of these two tests marks an important milestone of the collaboration, which is aimed at improving access to easy, rapid and low invasive blood-based molecular diagnostic testing for patients with mCRC. Both companies will now collaborate to make the tests commercially available to medical centers¹.

The fully automated Idylla™ ctKRAS Mutation Test (detecting 21 KRAS mutations, turnaround time 130 minutes) and the Idylla™ ctNRAS-BRAF Mutation Test (detecting 18 NRAS and 5 BRAF mutations, turnaround time 110 minutes) together target 44 mutations, each working directly on 1 ml of blood plasma with less than 1 minute hands-on time. The validation studies performed for the CE-marking of the Idylla™ ctRAS tests² showed high concordance of 88% between blood plasma based and tumor tissue based testing in patients with detectable levels of ctDNA, who typically are mCRC patients with liver metastases².

Understanding mCRC patients' individual biomarker status is key for timely treatment decision-making. As the Idylla™ ctRAS tests are designed to offer accurate and reliable molecular information quickly and efficiently, they can support clinical practice in performing integrated liquid biopsy RAS biomarker testing, independently of the laboratories' volume of testing or level of expertise.

Erwin Sablon, Head of R&D and Alliance Management of Biocartis, reacted: *"Liquid biopsy testing is at the advanced edge of oncology practice, where it has the ability to complement tissue testing and provide additional prognostic information that was not available to clinicians so far. We are delighted to have developed these liquid biopsy tests on Idylla™. As recommended in the guidelines³, RAS mutation testing is a critical component in mCRC clinical work-up, where patients with RAS wild-type tumors have been demonstrated to benefit from anti-EGFR therapies such as Erbitux® from Merck KGaA, Darmstadt, Germany. With these tests, we can now further improve the health outcome of mCRC patients across the world and we are happy to have partnered with Merck KGaA, Darmstadt, Germany in this endeavor."*

The development of liquid biopsy tests is a cornerstone of Biocartis' strategy to broaden access to molecular diagnostic testing through easy, rapid and less invasive molecular diagnostic solutions for patients across the world. Today, Biocartis has three liquid biopsy tests for research purposes available⁴, along with these two new IVD liquid biopsy RAS tests, the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test for patients with mCRC. A fourth liquid biopsy test, the Idylla™ ctEGFR Mutation Test, is currently under development.

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More information:



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¹ The collaboration does not include the US, China and Japan.

² Pre-treatment plasma samples from 198 mCRC patients enrolled in the prospective multicenter RASANC study were retrospectively assessed for the presence of ctDNA mutations in KRAS, NRAS and BRAF by the fully automated Idylla™ platform. B. Jacobs et al., "Evaluation of a fully automated extended RAS-BRAF test on prospectively collected plasma samples from patients with metastatic colorectal cancer", 2017, Journal of Clinical Oncology, ASCO, http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.e15127

³ ESMO/NCCN guidelines.

⁴ The Idylla™ ctBRAF Mutation Assay, the Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay are Research Use Only (RUO), not for use in diagnostic procedures.

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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 twelve oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis_.

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Forward-looking statements

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