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Biocartis launches CE-marked IVD NRAS test for colorectal cancer

Mechelen, Belgium, **23 May 2017 -** Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of the Idylla™ NRAS Mutation Test. This newly launched CE-marked IVD test, alongside Biocartis' existing Idylla™ NRAS-BRAF Mutation Test (CE-IVD), will now allow for more flexibility in geographies where BRAF testing for metastatic colorectal cancer (mCRC) patients is not reimbursed.

Access to rapid and easy-to-use molecular diagnostic tests is essential to understand what specific gene mutations drive cancers. This allows for timely cancer treatment decision-making. About five percent of all metastatic colorectal tumors are driven by mutations in the NRAS oncogene[1] and as such NRAS mutation testing for mCRC patients is recommended by the most recent clinical guidelines. The Idylla™ NRAS Mutation Test[2] detects 18 NRAS mutations directly from a single slice of FFPE[3] tumor tissue in approx. two hours, with less than two minutes hands-on time.

The test is yet another addition to Biocartis' colorectal cancer test offering, now consisting of three CE-marked solid biopsy tests (together detecting 44 mutations directly from a slice of FFPE tumor tissue each) and two liquid biopsy assays[4] available for research use only (together detecting 46 mutations directly from 1 ml of blood plasma each).

Hilde Eylenbosch, Chief Commercial Officer Biocartis, commented: *"The launch of the Idylla™ NRAS Mutation Test as a CE marked IVD test demonstrates we are on top of our customer demands. This NRAS test for colorectal cancer patients will respond to existing market needs of both laboratories and hospitals on the one hand, and our pharmaceutical partners on the other hand, in geographies where BRAF testing for metastatic colorectal cancer (mCRC) patients is not reimbursed. Additionally, it further completes our colorectal cancer test offering on Idylla™, that is today already one of the most advanced, rapid and easy-to-use molecular diagnostic test offerings on the market."*

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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 nine oncology tests and two infectious disease tests. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

[1] Jean-Yves Douillard, M.D., Ph.D., Kelly S. Oliner, Ph.D., Salvatore Siena, M.D., et al. Panitumumab–FOLFOX4 Treatment and RAS Mutations in Colorectal Cancer. N Engl J Med 2013;369:1023-34.
[2] The Idylla™ NRAS Mutation Test, performed on the Biocartis Idylla™ system, is an in vitro diagnostic test for the qualitative detection of NRAS mutations in codons 12, 13, 59, 61, 117 and 146 of the NRAS oncogene. More information on www.biocartis.com.
[3] Formalin-fixed paraffin embedded.
[4] The Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test are CE-marked IVD tests which can be used in diagnostic procedures. The Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay are Research Use Only (RUO) and not for use in diagnostic procedures.

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