



PRESS RELEASE

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CE-marking Idylla™ NRAS-BRAF Mutation Test completes offering of metastatic colorectal cancer tests for clinical use on Idylla™ platform

Mechelen, Belgium, 15 December 2016 - Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the CE-marking of its solid biopsy Idylla™ NRAS-BRAF Mutation Test. Together with the CE-marked Idylla™ KRAS Mutation Test, Biocartis is now able to offer its customers a complete testing for metastatic colorectal cancers¹ (mCRC) for clinical use on its Idylla™ molecular diagnostics platform, as recommended by the most recent clinical guidelines. The ability of Biocartis' RAS test offering to enable same-day results can now open routes towards faster treatment selection for mCRC patients.

Colorectal cancer is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually². Operating directly from so-called formalin-fixed paraffin embedded (FFPE) tumour slices, the fully automated Idylla™ NRAS-BRAF Mutation Test uniquely combines, in a single-tissue biopsy test, the detection of 18 NRAS and 5 BRAF mutations at high sensitivity. This follows the latest clinical practice recommendations of the American Society of Clinical Oncology (ASCO)³ and the European Society for Medical Oncology (ESMO)⁴ which, next to KRAS and NRAS testing, now also recommend testing on BRAF mutations as most frequently occurring mutations in colorectal cancer.

Together with its existing Idylla™ KRAS Mutation Test that detects 21 mutations, the Biocartis colorectal cancer test offering now allows simultaneous detection of 44 so-called clinically actionable targets for colorectal cancer. The obtained CE-marking of the Idylla™ NRAS-BRAF Mutation Test is an important driver in the further market adoption of Idylla™.

Rudi Pauwels, Chief Executive Officer of Biocartis, commented: "Many of our European customers as well as our distribution partners have been awaiting the CE-mark of our Idylla™ NRAS-BRAF Mutation Test. Together with our existing CE-marked Idylla™ KRAS Mutation Test for colorectal cancer, which was recently rewarded in a study⁵ by the global pharmaceutical company AstraZeneca as being the fastest, most easy to use and one of the most accurate high precision tests compared to peers, Biocartis now has a full CE-marked colorectal cancer mutations test panel. This panel allows for complete same-day testing and treatment selection for mCRC patients. As such, we expect this CE-marking to add substantial traction to our commercial cartridge consumption."

The Idylla™ NRAS-BRAF Mutation Test is the fourth CE-marked IVD test for Biocartis in its offering of easy-to-use, rapid and highly accurate diagnostic tests for the Idylla™ molecular diagnostics platform.

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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 Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available at: <http://globocan.iarc.fr>. Last accessed November 2016.

³ Allegra et al, Extended RAS Gene Mutation Testing in Metastatic Colorectal Carcinoma to Predict Response to Anti-Epidermal Growth Factor Receptor Monoclonal Antibody Therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015, J Clin Oncol 2016, 34:179-185, <http://ascopubs.org/doi/pdf/10.1200/jco.2015.63.9674>. See also <http://gicasymp.org/asco-updates-guideline-include-testing-new-ras-mutations>.

⁴ Van Cutsem et al, ESMO consensus guidelines for the management of patients with metastatic colorectal cancer, Annals of Oncology 2016, 8:1386-1422.

⁵ James L. Sherwood et al, 2016, Implications of Key Differences Across 12 KRAS Mutation Detection Technologies and Their Relevance in Clinical Practice, first presented at ESMO, 10 October 2016, available for download at https://media.biocartis.com/biocartis/documents/Sherwood_KRAS_2016_ESMO_91P.pdf.

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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