



PRESS RELEASE

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## Study demonstrating high performance of Idylla™ liquid biopsy RAS tests to be presented at ASCO Annual Meeting

**Mechelen, Belgium, 18 May 2017** - Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a study abstract<sup>1</sup> demonstrating the high performance of Biocartis' recently launched Idylla™ ctRAS liquid biopsy assays, which will be presented at the renowned ASCO Annual Meeting of the American Society of Clinical Oncology between June 2-6 in Chicago, US. The ASCO Annual Meeting is attended by more than 30,000 oncology professionals from all over the world.

Understanding the individual gene mutations that drive a cancer is essential for timely cancer treatment decision-making. In many hospitals and laboratory settings, RAS biomarker testing is not available due to the technical complexity of conventional test methods. Consequently, samples often have to be shipped to reference laboratories for analysis, which results in long turnaround times. Additionally, tumor tissue from metastatic patients is not always available or accessible in time.

In the study, conducted in collaboration with Prof. Pierre-Laurent Puig (Paris, France), plasma samples from 198 patients with metastatic colorectal cancer (mCRC) were used to compare the Idylla™ ctKRAS Mutation Assay (RUO<sup>2</sup>) and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO) to a deep Next-generation sequencing (NGS) reference method<sup>3</sup>. The Idylla™ assays used in the study require only 1 ml of plasma each, which was added directly into the Idylla™ cartridge, resulting in less than one minute hands-on time and a turnaround time of less than 130 minutes.

The comparison resulted in an overall concordance of 97%. As such, the study concluded that Biocartis' Idylla™ ctRAS liquid biopsy assays enable rapid and highly reliable detection of mutations in the RAS genes, which occur in around 50%<sup>4</sup> of mCRC patients.

The Idylla™ ctKRAS Mutation Assay (RUO) and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO) were developed under the partnership with Merck KGaA (Darmstadt, Germany), announced in January 2016. Under the same partnership, CE-marked IVD versions of the liquid biopsy RAS biomarker assays are expected to be launched in the second half of 2017.

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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

<sup>1</sup> Jacobs et al., "Evaluation of a fully automated extended RAS-BRAF test on prospectively collected plasma samples from patients with metastatic colorectal cancer", to be presented at ASCO, June 2-6, 2017.

<sup>2</sup> Research Use Only, not for use in diagnostic procedures.

<sup>3</sup> As a comparator test, NGS analysis with a sensitivity of 0.2% was performed on extracted plasma ctDNA according to Pécuchet et al. (2016).

<sup>4</sup> 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.

infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers eight oncology tests and two infectious disease tests. More information: [www.biocartis.com](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

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