



PRESS RELEASE

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Biocartis Abstract on Performance Idylla™ ctRAS Liquid Biopsy Tests Selected for Oral Presentation at 2018 American Association for Cancer Research Meeting

Mechelen, Belgium, 15 March 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that [a study abstract](#)¹ on the analytical and clinical validation of the liquid biopsy Idylla™ ctKRAS and ctNRAS-BRAF Tests² has been selected for oral presentation at the renowned AACR (American Association for Cancer Research) Annual Meeting in Chicago (US), taking place between 14-18 April 2018. Results demonstrated that the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests³ provide a sensitive, reliable and fast solution for liquid biopsy RAS-BRAF ctDNA (circulating tumor) testing, and that RAS-BRAF mutation status can be adequately determined using blood plasma from metastatic colorectal cancer (mCRC) patients with liver metastases.

RAS-BRAF mutation analysis is mandatory by all major international guidelines⁴ for mCRC patients. Incorporating ctDNA testing in routine diagnostics could allow rapid detection of baseline RAS mutation status from a single blood draw. Today, an increasing number of studies is aimed at supporting the use of liquid biopsy testing in routine diagnostics.

The analytical and clinical validation of the liquid biopsy Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test, both CE-marked in December 2017, is based on a RAS concordance comparison study between tumor tissue (FFPE⁵) and blood plasma samples^{6,7}. For clinical validation, pre-treatment plasma samples from 203 mCRC patients were retrospectively assessed. As a comparator test, NGS analysis was performed on ctDNA⁸, resulting in overall RAS agreement between Idylla™ and NGS on plasma of 90.0%, showing high clinical sensitivity of the liquid biopsy Idylla™ tests.

Additionally, the study demonstrated that patients with low amounts of ctDNA in the blood sample, absence of liver metastases and resected primary tumor were associated with discordant RAS results between FFPE tumor and blood plasma samples, whereas in the patient population with liver metastases showing sufficient ctDNA, overall RAS agreement between plasma and tissue RAS status was 92.5%⁹. As such, the study concluded that the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests, operating each directly on 1 ml of blood plasma on the Biocartis Idylla™ system, provide a sensitive, reliable and fast solution for RAS-BRAF ctDNA testing in mCRC patients with liver metastases.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We are very proud that the excellent performance of our liquid biopsy Idylla™ RAS tests has been selected for an oral presentation at the renowned 2018 AACR Meeting. We see this as recognition by the AACR of the huge potential of using liquid biopsy tests such as ours in routine clinical diagnostics. This furthermore confirms the true strength of our Idylla™ system as a flexible solution for all patients, whether they have high or low amounts of ctDNA in the blood stream, as Idylla™ allows for easy, rapid and sensitive molecular diagnostic testing on both FFPE tumor tissue and blood plasma samples."*

Colorectal cancer is the third most common cancer worldwide, with nearly 1.4 million new cases diagnosed in 2012¹⁰.

¹ B Jacobs, B Claes, P Laurent-Puig, JP Bachelot, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018.

² These tests were developed under the collaboration with Merck KGaA, Darmstadt, Germany.

³ The Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test are CE-marked IVD's in Europe and not for sale in the US. Please check availability with the local Biocartis sales representative.

⁴ http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm; ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Annals of Oncology* 0: 1-37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. 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. *Journal of Clinical Oncology* 2016; 34(2):179-85) and CAP/AMP/ASCO

⁵ Formalin-fixed, paraffin embedded.

⁶ The prospective multicenter RASANC study: "RAS mutations concordance in circulating tumour DNA (ctDNA) and tissue in metastatic colorectal cancer (mCRC)"; J.B. Bachelot et al, Poster presented at ASCO 2017, Sponsored by AGEO – supported by a grant from Merck Serono s.a.s. (France), an affiliate of Merck KGaA, Darmstadt, Germany.

⁷ Patients enrolled in the prospective multicenter RASANC study (NCT02502656). Proper informed consent and statistical analysis were included.

⁸ As a comparator test, NGS analysis with a sensitivity of 0.2% was performed on ctDNA according to Pécuchet et al. (2016). In addition, tissue RAS/BRAF results were available from standard of care testing.

⁹ With a sensitivity of 93.2% and specificity of 90.9%.

¹⁰ World Cancer Research Fund International, <http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics>, last consulted on 26 January 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 infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers fourteen 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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