



PRESS RELEASE

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Strong performance data of proprietary MSI Biomarkers for the Idylla™ MSI Test to be published at ESMO

Mechelen, Belgium, 31 August 2017 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the [publication of two study abstracts](#)¹ regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI)² that are to be included in the Idylla™ MSI Test (the 'MSI Biomarkers'). Both abstracts show superior performance of the MSI Biomarkers compared to the reference methods. The respective studies have been selected for presentation at the renowned European Society for Medical Oncology (ESMO) congress in September 2017.

Microsatellite instability is the result of errors in the body's so-called DNA mismatch repair system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, resulting in potential tumor growth. Today, MSI testing is recommended in several guidelines³ for all colorectal cancers (CRC), but MSI is present in several other tumor types as well, such as gastric cancer. Additionally, MSI is the sole independent factor that may predict a patient's response to certain immunotherapies⁴.

The [two studies¹ that will be presented at ESMO](#), of which one was performed in collaboration with the leading science and technology company Merck KGaA, Darmstadt, Germany⁵, show strong performance of Biocartis' MSI Biomarkers for the detection of MSI status in gastric and colorectal cancer samples.

Detection of MSI with a novel panel of biomarkers in gastric cancer samples

The first study⁶, performed in collaboration with Merck KGaA, Darmstadt, Germany⁵, successfully demonstrated the detection of MSI status in 150 gastric cancer samples. The study showed 100% overall agreement with the Promega MSI analysis reference method for valid results⁷. In total, 11% of the samples tested with the reference method failed, even after repeat testing, whereas the MSI Biomarkers generated a result for all of the performed tests.

Detection of MSI in colorectal cancer samples

The second study⁸ included 870 samples and successfully demonstrated the detection of MSI status in colorectal cancer samples, based on a 94% overall agreement with a reference method⁹. Subsequent discordance testing showed that the Biocartis MSI Biomarkers detected 6% more MSI-high status in comparison with the reference method. In total, 12% of the tests performed with the reference method failed, even after repeat testing, compared to a 4% failure rate with the MSI Biomarkers.

¹ De Craene et al., "Detection of microsatellite instability (MSI) with a novel panel of biomarkers in gastric cancer samples", 2017; and Maertens et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with the automated Idylla™ MSI Test", 2017, to be presented as ESMO, 8-12 September 2017, Madrid, Spain and published in the ESMO 2017 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

² Zhao et al. 2014; eLife.

³ NCCN Guidelines Colon Cancer version 2017.1; and, Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386-1422.

⁴ Recent data have shown that advanced CRC patients with an MSI-high status respond particularly well to certain immunotherapies (Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. Cancer Discov. 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372, 2509-2520).

⁵ Biocartis and Merck KGaA, Darmstadt, Germany collaborated on the study for detection of MSI with a novel panel of biomarkers in gastric cancer samples. Furthermore, Biocartis is collaborating with Merck KGaA Darmstadt, Germany on the development and commercialization of new liquid biopsy RAS biomarker tests for metastatic colorectal cancer (mCRC).

⁶ De Craene et al., "Detection of microsatellite instability (MSI) with a novel panel of biomarkers in gastric cancer samples", 2017, to be presented as ESMO, 8-12 September 2017, Madrid, Spain and published in the ESMO 2017 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

⁷ Promega MSI analysis system.

⁸ Maertens et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with the automated Idylla™ MSI Test", 2017, to be presented as ESMO, 8-12 September 2017, Madrid, Spain and published in the ESMO 2017 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

⁹ To assess the suitability of the novel marker set to detect MSI status in CRC, 8 or more markers were profiled in 870 CRC samples. Several clinical sites and different ethnic groups (Afro American, Caucasian, East-Asian, Hispanic and Indian) were included to assess robustness of marker selection. Repeat length was determined on FFPE DNA by PCR followed by melting curve analysis. Two-hundred and one samples were additionally screened with a reference methodology for MSI detection (Promega MSI analysis system).

The MSI Biomarkers have been identified by Prof. Diether Lambrechts' laboratory (VIB-KU Leuven Center for Cancer Biology, Belgium) and were exclusively licensed to Biocartis in 2013 from the VIB (Flanders Institute for Biotechnology). Today's commonly used MSI testing techniques are expensive, manual, lengthy and complex to perform, often resulting in test failures. The Idylla™ MSI Test will combine the unique set of MSI Biomarkers with the unique features of the Idylla™ platform, enabling actionable results from just one FFPE¹⁰ tumor slice, and requiring no additional healthy tissue control sample. This could allow broader access to MSI testing.

The Biocartis Idylla™ MSI Test is currently under development and is expected to be launched in 2018.

Geert Maertens, Chief Scientific Officer of Biocartis, reacted: *"Today, many laboratories and hospitals have expressed the need for a rapid, more reliable and easy-to-perform MSI test, as current MSI testing methods are cumbersome, lack specificity and as such are underutilized. Based on these studies, MSI testing with Idylla™ shows great potential, both in terms of expanding its diagnostic use to other cancer domains such as gastric cancer, as evolving towards its full potential as a prognostic test for colorectal cancer and a predictive test for certain immunotherapies¹¹. With currently some 240 cancer immunotherapies in the pipeline¹², we expect large healthcare companies to play an important role in the further market growth of MSI testing."*

Taking place between 8-12 September 2017 in Madrid (Spain), the ESMO congress is considered the most influential annual meeting for oncology professionals in Europe.

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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 ten 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

This press release may contain forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements speak only as of the date of this press release. Biocartis expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release. You should not place undue reliance on forward-looking statements.

¹⁰ Formalin-fixed, paraffin embedded.

¹¹ Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. *Cancer Discov.* 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. *N Engl J Med* 372, 2509-2520.

¹² Source: PhRMA, "Medicines in Development for Immuno-Oncology 2017 Report", <http://www.pharma.org/medicines-in-development-immuno-oncology>, last consulted on 18 July 2017.