

Biocartis announces CE-IVD marking of its Idylla™ MSI Test

Mechelen, Belgium, 28 February 2019 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the CE-IVD marking of its fully automated Idylla™ MSI Test which allows for fast and accurate information on a patient's MSI status directly from a single sample of FFPE¹ colorectal cancer tumor tissue. This CE-IVD launch is a key addition to Biocartis' colorectal cancer (CRC) Idylla™ test menu as MSI detection is currently recommended for all patients with CRC².

MSI is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, contributing to tumor growth and evolution. MSI-High status is found in about 15% of CRC tumors³. About 16% of these MSI-High colorectal cancers may be associated with Lynch Syndrome³, which is one of the most common hereditary cancer syndromes and results in a significantly increased risk of developing CRC or other cancers such as endometrial or breast cancer⁴.

MSI testing today is recommended for all colorectal and endometrial cancers⁵ but is still underused since current methods are highly complex. The Idylla™ MSI Test has been developed to overcome these drawbacks. It is a fully automated test that provides information on the MSI status⁶ (i.e. Microsatellite Instability-High (MSI-H) or Microsatellite Stable (MSS)) of CRC tumors within approximately 150 minutes from just one slice of FFPE¹ tumor tissue, without the need of a reference sample. The test shows high concordance⁷ (>97%) and lower failure rates compared to standard methods. The unique aspects of the Idylla™ MSI Test could enable a broader penetration of MSI testing.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "We are excited to announce today the CE-IVD marking of the Idylla™ MSI Test which is now available for clinical use in CRC patients. This test truly matches the mission of Biocartis to make innovative MDx testing accessible to all patients worldwide. Thanks to the unique features of this test, MSI testing is now easy, rapid and accessible to a much larger patient population."

In addition to applications for CRC, MSI is believed to be an independent factor that may predict a patient's response to certain immunotherapies⁸. As such, expansion opportunities for the Idylla™ MSI Test into that domain will be explored in the future.

More information on the Idylla™ MSI Test can be found [here](#) on the website of Biocartis.

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1 FFPE = formalin fixed, paraffin embedded.

2 Source: NCCN Guidelines, <https://www.nccn.org/patients/guidelines/colon/22/>, last consulted on 20 February 2019.

3 An MSI test looks for changes in the DNA sequence between normal tissue and tumor tissue and can identify whether or not there is high amount of instability, which is called MSI-High. MSI testing with CRC patients is important to see if the CRC is hereditary (meaning the patient has Lynch syndrome), because in such case there is a risk that their family members could also have an increased chance of developing colorectal or other tumors. Source: <https://fightcolorectalcancer.org/fight/diagnosis/what-is-msi-and-mss/> and <https://www.asco.org/about-asco/press-center/news-releases/genomic-study-finds-lynch-syndrome-common-among-people-msi>, last consulted on 7 February 2019.

4 Source: <https://www.cancer.net/cancer-types/lynch-syndrome>, last consulted on 20 February 2019.

5 Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC.

6 Clinical Performance Study showed 99,7% concordance for MSI testing vs Promega (unpublished data); De Craene et al. (2018) Journal of Clinical Oncology 36:15 suppl, e15639; De Craene et al. (2017) Annals of Oncology 28 (suppl_5): v209-v268; Maertens et al. (2017) Annals of Oncology 28 (suppl_5): v22-v42.

7 The Idylla™ MSI Test uses a new set of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A & SULF2 genes, which were exclusively licensed to Biocartis in 2013 from VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium). These MSI biomarkers are tumor-specific, show a high frequency in colorectal and endometrial cancers and are stable across different ethnicities ensuring excellent specificity of the assay.

8 In a recent study in collaboration with Prof. Diether Lambrechts (VIB-KU Leuven, Belgium) presented at ASCO, the number of Idylla™ MSI Biomarkers were shown to be associated with total indel load and tumor mutational burden in endometrial tumors and in colorectal cancer (source: Zhao et al. J Clin Oncol 36, 2018 (suppl); abstr e15654).

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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 is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology. This area represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis_.

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Forward-looking statements

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