



PRESS RELEASE

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Biocartis Announces Publication of Large Multi-Center Comparison Study with Idylla™ MSI Assay Showing Very Low Failure Rates and Excellent Concordance with Reference Methods

Mechelen, Belgium, 17 November 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a global multi-center real world study¹ with its Idylla™ MSI Assay. This multi-center study is the largest so far for Biocartis and demonstrates excellent performance of the Idylla™ MSI Assay² with a very low failure rate.

In this real-world global study, 44 clinical centers performed Idylla™ MSI testing on 1,301 archived colorectal cancer FFPE³ tissue sections. Idylla™ results were compared against routine diagnostic testing in those sites, demonstrating excellent concordance with immunohistochemistry (96%⁴) and routine molecular methods (98%)⁵. Additionally, the failure rate of the Idylla™ MSI Assay was very low (0.23%; 3/1301), underlining the robustness of the Idylla™ MSI Assay.

Microsatellite instability (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. Microsatellite instability (MSI) is present in 15–20% of primary colorectal cancers and MSI status is assessed to detect Lynch syndrome⁶, guide adjuvant chemotherapy, determine prognosis, and use as a companion test for checkpoint blockade inhibitors. Traditionally, MSI status is determined by immunohistochemistry⁷ or molecular diagnostic testing methods. Although it is recommended for all colorectal, endometrial and several other cancers⁸, MSI testing remains underused today since current methods are highly complex.

The fully automated [Idylla™ MSI Test](#)⁹ (CE-IVD) was developed to overcome these drawbacks and provides information on the MSI status¹⁰ within approximately 150 minutes from just one slice of FFPE tumor tissue, without the need for a reference sample.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We are pleased with this very large and strong data set for our Idylla™ MSI Test. MSI is increasingly used as a biomarker that guides therapies or determines prognosis for a growing number of cancers. We believe that the unique aspects of the Idylla™ MSI Test, which clearly shows great advantages over current MSI testing methods on the market, could enable a broader penetration of MSI testing. Very large, global studies such as these really contribute to show the unique features of our Idylla™ MSI Test."*

The study is published in Virchows Archive¹ and is available online [here](#). The [Idylla™ MSI Test received its CE-marking](#) on 28 February 2019. For more info, go to the [Biocartis website](#).

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1 A. Velasco et al., Multi-center real-world comparison of the fully automated Idylla™ microsatellite instability assay with routine molecular methods and immunohistochemistry on formalin-fixed paraffin-embedded tissue of colorectal cancer, Virchows Archiv <https://doi.org/10.1007/s00428-020-02962-x>, November 2020

2 RUO = Research Use Only, not for use in diagnostic procedures

3 FFPE = formalin-fixed, paraffin-embedded

4 17/37 discordant samples were found to be concordant with the Idylla™ result when a third method was used

5 Third-method analysis found concordance with the Idylla™ result for 8/16 discordant samples

6 Which is one of the most common hereditary cancer syndromes and results in a significantly increased risk of developing colorectal or other cancers such as endometrial or gastric cancer. 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 12 November 2020

7 Immunohistochemistry is a laboratory method that uses antibodies to check for certain antigens (markers) in a sample of tissue. It's used to help diagnose diseases, such as cancer. It may also be used to help tell the difference between different types of cancer. Source: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunohistochemistry>, last consulted on 12 November 2020

8 Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC, last consulted on 12 November 2020

9 The Idylla™ MSI Test is intended for the qualitative detection of a novel panel of seven monomorphic homopolymer biomarkers for identification of colorectal cancers (CRC) with microsatellite instability (MSI)

10 i.e. Microsatellite Instability-High (MSI-H) or Microsatellite Stable (MSS)

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 continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis_.

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