Idylla™ MSI Performance Study
Selected for Publication at ASCO Conference

Mechelen, Belgium, 16 May 2019 – Biocartis Group NV (the ‘Company’ or ‘Biocartis’), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that a multi-centered1 study on the performance of the Idylla™ MSI Test (CE IVD) in comparison with the Promega MSI test2 (‘Promega MSI Test’) has been selected for publication at the renowned ASCO (American Society of Clinical Oncology) Annual Meeting. The study showed high performance and a low invalid rate of the Idylla™ MSI Test, as such demonstrating the possibility of rapid, fully automated MSI testing with Idylla™. The ASCO conference takes place between 30 May and 4 June 2019 in Chicago (IL), US.

The performance study was conducted in cooperation with the University Hospital Antwerp (Belgium) and the University Hospital Aarhus (Denmark) and compared the detection of microsatellite instability (MSI) in colorectal cancer (CRC) samples with the Idylla™ MSI Test and the Promega MSI Test, the latter also requiring a second sample for control or reference when being performed. On a total of 330 FFPE3 tumor samples, the tests showed a concordance rate of 99.7%. Furthermore, the Idylla™ MSI Test demonstrated invalid results on 0.6% of the samples compared to the Promega MSI Test with 2.1%.

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 tumors but also in other cancers such as endometrial, gastric, breast, lung and prostate cancer4.

MSI testing5 today is recommended for all colorectal and endometrial cancers4, but is still underused as current MSI testing methods are complex and therefore not available outside of highly specialized laboratories. The Idylla™ MSI Test has been developed to overcome these drawbacks. It is a fully automated test that provides information on the MSI status7 (i.e. Microsatellite Instability-High (MSI-H) or Microsatellite Stable (MSS)) of CRC tumors within approximately 150 minutes from just one slice of FFPE tumor tissue, without the need of a reference sample. These unique aspects could enable a broader penetration of MSI testing, worldwide.

The Idylla™ MSI Test is a key addition to Biocartis’ colorectal cancer (CRC) Idylla™ test menu and was launched as a CE-marked IVD Test on 28 February 2019. Furthermore, on 12 March 2019 Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY) aimed at the potential registration as a companion diagnostic8 and use of the Idylla™ MSI test in connection with immuno-oncology therapies.

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1 Pauwels P. et al, ‘The Idylla™ MSI Test multi-center concordance study: microsatellite instability detection in colorectal cancer samples’; first published at ASCO Annual Meeting of the American Society of Clinical Oncology, 30 May – 4 June 2019, Chicago (IL), US.
2 The Promega MSI Analysis System v1.2 (Promega MSI)
3 Formalin fixed, paraffin embedded.
4 Source: www.asco.org/endorsements/HereditaryCRC.
6 A CDx test is a test used as a companion to a therapeutic drug that helps predict if a patient is likely to respond to a treatment or not.
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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