PRESS RELEASE 16 May 2019, 07:00 CEST

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-centered[1] study on the performance of the Idylla™ MSI Test (CE IVD) in comparison with the Promega MSI test[2] ('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 FFPE[3] 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 cancer[4].

MSI testing[5] today is recommended for all colorectal and endometrial cancers[6], 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 status[7] (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 diagnostic[8] 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: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5953403/, last consulted on 13 May 2019.
[5] 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/, last consulted on 13 May 2019.
[6] Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC.
[7] 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.
[8] 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_.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.