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Biocartis Announces US FDA 510(k) submission of its Idylla™ MSI Test

First US FDA Oncology Assay Submission for Biocartis

Mechelen, Belgium, 20 April 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the US FDA 510(k) submission[1] of its Idylla™ MSI Test[2] for use as an *in vitro* diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome.

MSI is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system, which normally spontaneously corrects errors that occur during DNA replication. In case this MMR system does not function properly, microsatellite instability occurs. MSI-High (MSI-H) is detected in approximately 15% of all colorectal cancers and 3% are associated with Lynch syndrome, whereas the other 12% have sporadic disease[3]. Lynch syndrome is the most common cause of hereditary colorectal cancer and is caused by inherited changes (mutations) in genes that affect DNA mismatch repair[4].

Today, MSI testing is recommended for patients with colorectal cancer for screening for Lynch syndrome[5]. However, it is still underused since current methods are highly complex. The Idylla™ MSI Test has been developed to overcome these drawbacks. As a fully automated test, it provides information on the MSI status[6] of CRC tumors within approximately 150 minutes from just one slice of formalin-fixed, paraffin-embedded (FFPE) tumor tissue, without the need of a reference sample.

Commenting on the US FDA 510(k) submission of the Idylla™ MSI Test, Herman Verrelst, Chief Executive Officer of Biocartis, said: "*This is a major milestone for the Company as this is Biocartis' first US FDA submission of an oncology assay. Once the 510(k) clearance is obtained, both large and small US labs are expected to benefit from this fast and easy to use Idylla™ MSI testing thanks to the fully automated sample-to-result nature of our platform. We continue to build momentum in our regulatory program and plan to submit more products to the US FDA, also supported by our pharma partners.*"

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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 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: @Biocartis_.

1 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 19 April 2021
2 The Idylla™ MSI Test, for use on the Idylla™ system, is intended for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors and to aid in the differentiation between sporadic CRC and potential Lynch Syndrome. The clinical performance of this device to guide treatment of MSI-H patients has not been established. The Idylla™ MSI Test uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of seven monomorphic biomarkers and subsequent melt-curve analysis. The Idylla™ MSI Test uses a novel set of short homopolymers 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)
3 Dudley JC et al. (2016) Microsatellite instability as a biomarker for PD-1 blockade. Clin Cancer Res. 22(4):813–820
4 Source: CDC, last consulted online here on 19 April 2021
5 Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer V.2.2018. Accessed 25 July 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org
6 The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid

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.