PRESS RELEASE

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BIOCARTIS ANNOUNCES THE US FDA 510(k) CLEARANCE FOR THE IDYLLA™ MSI TEST

Mechelen, Belgium, 2 March 2023 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the U.S. Food and Drug Administration (FDA) 510(k) clearance[1] for its fully automated Idylla™ MSI Test. This 510(k) clearance reinforces Biocartis' commitment to enable clinical molecular diagnostics in the U.S. Now, labs of all sizes can benefit from Idylla™'s high sensitivity, unmatched ease-of-use, and rapid turnaround times.

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[2]. 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[3].

The Idylla™ MSI Test is cleared for in-vitro diagnostic use on the Biocartis Idylla™ System only. The Idylla™ MSI Test, for use on the Idylla™ System, 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 (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) and subsequent melt-curve analysis. The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid. Idylla™ MSI Test is indicated for use by healthcare professionals for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors, indicative of mismatch repair deficiency, as an aid in the identification of potential Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome. The results from the Idylla™ MSI Test should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data. The Idylla™ MSI Test should not be used for diagnosis of CRC. The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

The Idylla™ MSI Test is a fully automated test, that provides information on the MSI status of CRC tumors within approximately 150 minutes from just one section of formalin-fixed, paraffin-embedded (FFPE) tumor tissue, without the need for paired normal tissue sample.

Commenting on the U.S. Food and Drug Administration (FDA) 510(k) clearance Herman Verrelst, Chief Executive Officer of Biocartis said: *"This first US FDA 510(k) clearance of an oncology assay is a major milestone for the Company. 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 can now start to commercialize our in-vitro diagnostic solution for clinical use, which will unlock significant additional market potential and pave the way for continued strong growth of our oncology business in the U.S. We continue to build momentum in our regulatory program and plan to submit more products to the U.S. FDA, also supported by our pharma partners."*

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About Biocartis

With its revolutionary and proprietary Idylla™ platform, Biocartis (Euronext Brussels: BCART) aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. Idylla™'s continuously expanding menu of molecular diagnostic tests address key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung and liver cancer, as well as for COVID-19, Flu, RSV and sepsis. For more information, visit www.biocartis.com or follow Biocartis on Twitter @Biocartis_ , Facebook or LinkedIn.

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.

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[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). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 28 February 2023

[2] Dudley JC et al. (2016) Microsatellite instability as a biomarker for PD-1 blockade. Clin Cancer Res. 22(4):813–820

[3] Source: CDC, last consulted online here on 27 February 2023