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Biocartis Announces New Immuno-Oncology Project with Bristol-Myers Squibb Aimed at Registration of Idylla™ MSI test in China

Mechelen, Belgium, 5 March 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces a new project under its existing collaboration[1] with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company. The existing collaboration aims at the potential registration and use as a companion diagnostic[2] (CDx) of the Idylla™ MSI test in connection with immuno-oncology therapies of Bristol-Myers Squibb. The initial focus under the collaboration is to achieve registration in the United States of the Idylla™ MSI test as a CDx test in metastatic colorectal cancer (mCRC). Bristol-Myers Squibb and Biocartis have now agreed to add a new project under their collaboration which pursues the registration of the Idylla™ MSI test as a CDx test in mCRC in the People's Republic of China.

MSI ('Microsatellite Instability') is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that spontaneously occur during the normal process of DNA replication are no longer corrected, contributing to tumor growth and evolution. Approximately 15% of colorectal (CRC) patients and 4-5% of mCRC patients have MSI-High or mismatch repair deficient (dMMR) biomarkers[3]. In addition to prognostic applications for CRC, MSI is believed to be an independent factor that may predict a patient's response to certain immunotherapies[4]. The fully automated and CE-marked IVD Idylla™ MSI Test provides information on the MSI status[5,6,7] of CRC tumors within approximately 150 minutes from just one slice of FFPE[8] tumor tissue, without the need of a reference sample.

Bristol-Myers Squibb's *Opdivo®* (nivolumab) plus low-dose *Yervoy®*[9] (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) mCRC that has progressed following treatment with certain chemotherapies[10].

Biocartis' joint venture Wondfo-Cartis[11] will commercialize the Idylla™ MSI test in the People's Republic of China upon obtaining regulatory approval.

Herman Verrelst, CEO of Biocartis, **commented**: "*We are pleased to announce this new immuno-oncology project in our ongoing collaboration with Bristol-Myers Squibb. Over the last years we actively expanded our commercial footprint to offer global collaboration opportunities to our pharma partners. Today's announcement shows the potential of that approach and marks a major milestone for our Chinese joint venture as this is its first companion diagnostics partnership. Especially in the Chinese market, many patients may benefit from the advantages of our Idylla™ MSI test as it has the potential to make MSI testing available to a broader population.*"

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1 On 12 March 2019
2 A companion diagnostic (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
3 Source: https://fightcolorectalcancer.org/fight/diagnosis/what-is-msi-and-mss/, last consulted on 3 March 2020
4 Ongoing research to support the hypothesis that MSI can be an independent factor to help predict a patient's response to certain immunotherapies, includes: Le *et al.* (2015) N-Eng-J-Med: 10.1056/NEJMoa1500596, showing that MMR status predicted clinical benefit of immune checkpoint blockade therapy; and Le *et al.* (2017) Science: 10.1126/science.aan6733, showing that MSI is associated with overall mutational and indel load of the tumor, neoantigen load, and lymphocyte infiltration of the tumor, and has been shown to be predictive for response to immunotherapies such as anti-PD-1 in a pan-cancer setting
5 Maertens *et al.* Annals of Oncology (2017) 28 (suppl_5): v22-v42
6 De Craene *et al.* Annals of Oncology (2017) 28 (suppl_5): v209-v268
7 De Craene *et al.* J Clin Oncol 36, 2018 (suppl; abstr e15639)
8 FFPE = formalin fixed, paraffin embedded
9 3 mg/kg Opdivo® plus 1 mg/kg Yervoy®. Approved in the United States.
10 Treatment with fluoropyrimidine, oxaliplatin and irinotecan
11 On 3 September 2018, Biocartis announced having entered into a joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, aimed at the commercialization of the Idylla™ platform in mainland China, within the field of oncology

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 in oncology. This 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. 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.