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# Biocartis and Bristol-Myers Squibb Sign Collaboration Agreement for MSI Testing with Immuno-Oncology Therapies

**Mechelen, Belgium, 12 March 2019** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, aimed at the potential registration as a companion diagnostic and use of the Idylla™ MSI test in connection with immuno-oncology therapies.

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. Understanding a person's MSI status may therefore be important for patient care. MSI-High status is found in various types of tumors[1], including approximately 15% of colorectal (CRC) tumors[2]. In addition to applications for CRC, MSI is believed to be an independent factor that may predict a patient's response to certain immunotherapies[3].

Bristol-Myers Squibb's *Opdivo* (nivolumab) plus low-dose *Yervoy*[4] (ipilimumab) is the first immuno-oncology combination treatment approved by the US Food and Drug Administration (FDA) for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies[5].

The fully automated Idylla™ MSI test, that received CE-IVD marking on February 28, 2019, provides information on the MSI status[6,7,8] of CRC tumors within approximately 150 minutes from just one slice of FFPE[9] tumor tissue, without the need of a reference sample.

The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the United States of the Idylla™ MSI test as a companion diagnostic test in mCRC.

**Herman Verrelst, CEO of Biocartis**, commented: "*We are proud to announce today a collaboration with Bristol-Myers Squibb, one of the world leaders in the area of immuno-oncology therapies. It is our belief that because of the advantages of our Idylla™ MSI test, MSI testing can potentially be made available to a broader patient population. This could open doors for a lot more patients to benefit from immunotherapies, matching the mission of Biocartis to make personalized medicine an everyday reality.*"

Financial details of the agreement are not disclosed.

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1 Including urothelial, prostate, pancreas, adreno-cortical, small bowel, sarcoma, mesothelioma, melanoma, gastric, and germ cell tumors (Latham et al. (2018) J Clin Oncol 36, 1-9. 10.1200/JCO. 18.00283.)
2 Source: https://fightcolorectalcancer.org/fight/diagnosis/what-is-msi-and-mss/, last consulted on 7 February 2019.
3 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.
4 3 mg/kg Opdivo plus 1 mg/kg Yervoy.
5 Treatment with fluoropyrimidine, oxaliplatin and irinotecan.
6 Maertens et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42.
7 De Craene et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268.
8 De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639).
9 FFPE = formalin fixed, paraffin embedded.

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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 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***

*This press release may contain forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements speak only as of the date of this press release. Biocartis expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements.*