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Biocartis launches innovative Idylla™ MSI Assay

Idylla™ MSI Assay further strengthens Biocartis' test menu and offers opportunities to enter the immuno-oncology testing market

Mechelen, Belgium, 17 July 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of its innovative and fully automated Idylla™ MSI[1] Assay (RUO[2]). The Idylla™ MSI Assay provides information on the MSI status[3,4,5] (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE[6] tumor tissue, without requiring a reference sample.

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. Current MSI testing methods rely on manual, lengthy and complex procedures involving amongst others obtaining and testing of a second reference sample.

The fully automated Idylla™ MSI Assay includes a novel set of seven MSI biomarkers, consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes. These 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).

Several multi-center studies[3,4,5] comparing the standard methods[7] with the Idylla™ MSI Assay showed a >95% concordance between results. Furthermore, compared to standard methods, the Idylla™ MSI Assay has a significantly lower failure rate[3,4,5], provides automated result reporting and includes MSI-specific pan-tumor biomarkers, independent of ethnicity[3,4,5].

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*Our fully automated Idylla™ MSI Assay, once validated for diagnostic use, will significantly strengthen our colorectal cancer test menu. This test is expected to overcome the drawbacks of conventional MSI testing, and could as such be made available to a much larger patient population. While the test is planned to initially be launched for colorectal cancer, MSI is present in several other tumor types as well, such as gastric and endometrial cancer, providing additional opportunities going forward. Finally, since MSI is an independent factor that may predict a patient's response to certain immunotherapies[8], we can now further explore opportunities to enter into the field of immuno-oncology[9] as the importance of MSI testing in that market is growing.*"

Dr. Alexander Mackinnon, Director - Clinical and Translational Research Core Lab at the Medical College of Wisconsin (US), reacted: *"Current MSI testing methods are often laborious and difficult to optimize. Furthermore, conventional MSI testing requires both normal and malignant tumor tissue. The Idylla™ MSI test is a simple, fully automated solution requiring only tumor tissue for the determination of MSI status. It provides rapid results that are highly concordant with conventional testing methods".*

The CE-marking of the Idylla™ MSI Assay for in vitro diagnostic use in colorectal cancer is anticipated in 2019.

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[1] MSI = microsatellite instability.
[2] Research Use Only, not for use in diagnostic procedures.
[3] Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42.
[4] De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268.
[5] De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.
[6] FFPE = formalin fixed, paraffin embedded.
[7] Including IHC and Promega MSI analysis system 1.2.
[8] In a recent study in collaboration with Prof. Diether Lambrechts (VIB-KU Leuven, Belgium) presented at ASCO, the number of Idylla™ MSI Biomarkers were shown to be associated with total indel load and tumor mutational burden in endometrial tumors and in colorectal cancer (source: Zhao et al. J Clin Oncol 36, 2018 (suppl; abstr e15654).
[9] Recent data have shown that advanced colorectal cancer patients with an MSI-high status respond particularly well to certain immunotherapies (Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. Cancer Discov. 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372, 2509-2520). MSI status is also used to screen for patients with potential hereditary colorectal cancer (the so-called 'Lynch syndrome') and can help to guide later genetic testing of the patient and relatives.

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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 launched the Idylla™ platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers fifteen oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Forward-looking statements

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