PRESS RELEASE

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Two Performance Studies on Idylla™ MSI Biomarkers Selected for Publication at ASCO Conference

Mechelen, Belgium, 17 May 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that two studies conducted in cooperation with the Flemish Institute for Biotechnology (VIB) regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI) that are included in the Idylla™ MSI Assay (the 'MSI Biomarkers'), have been selected for publication at the ASCO (American Society of Clinical Oncology) Annual Meeting, taking place between 1-5 June 2018 in Chicago, US. The first study uses the prototype Idylla™ MSI Assay in finalized design and shows superior performance of the MSI test compared to reference methods. The second study underlines the potential of Biocartis' MSI Biomarkers[1] to be used as a companion diagnostic to predict immunotherapy outcome in MSI-High[2] endometrial and colorectal tumors.

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. Detection of MSI is currently recommended for all patients with colorectal cancer (CRC). 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 is expected to overcome these drawbacks, providing results within 150 minutes from just one slice of FFPE[3] tumor tissue, without requiring a reference sample.

The first study[4] used the prototype Idylla™ MSI cartridges in a finalized design, containing a new set of seven MSI Biomarkers, consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes, to test 348 FFPE colorectal cancer samples[5] on their MSI status (i.e. MSI-High[2] or Microsatellite stable). A concordance analysis with a reference methodology[6] showed an overall agreement of 96.1%. Of the discordant results, fourteen cases were classified as MSI-High by Idylla™ but Microsatellite stable (11) or invalid (3) by the reference method. Based on these results, the study concluded that the prototype Idylla™ MSI Assay is capable of faster detection with excellent sensitivity and significantly less invalid results compared to reference molecular testing for MSI.

The second study[7], based on 33 samples, demonstrated that the MSI Biomarkers reliably identified MSI-High status in endometrial and colorectal cancer[8] and that MSI-High is correlated to the total insertion-deletion (indel) load of the tumor. These indel mutations increase tumor responsiveness to checkpoint blockade immunotherapies, which is a type of immunotherapy where the power of a patient's immune system is harnessed to attack tumors. Checkpoint blockade immunotherapies were recently US FDA approved for the treatment of MSI-High tumors. As such, the study concluded that the MSI Biomarkers could potentially be used to predict immunotherapy outcome in MSI-High tumors.

Prof. Diether Lambrechts, Director of the VIB – KU Leuven Center for Cancer Biology, commented: *"These studies clearly show the high clinical value of the MSI Biomarkers, first identified in our lab and now meticulously further selected to a set of seven biomarkers by Biocartis that are combined with the advantages of the fully automated Idylla™ system. The seven biomarkers show a remarkable association with both tumor*

[1] The MSI Biomarkers were identified by Prof. Diether Lambrechts' laboratory and exclusively licensed to Biocartis from VIB in 2013.
[2] MSI-High tumors share certain characteristics, such as high tumor mutation burden with a high number of insertion-deletion (indel) mutations, which are likely to result in the production of neo-antigens, attracting the adaptive immune system and therefore more likely to respond to checkpoint blockade immunotherapies. Antigenicity is the capacity of a molecule or an antigen to induce an immune response that is to be recognized by and interact with an immunologically specific antibody or T-cell receptor. (Source: https://www.biology-online.org/dictionary/Antigenicity, last consulted online on 17 April 2018).
[3] FFPE = formalin fixed, paraffin embedded.
[4] B. De Craene et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US.
[5] Patient samples of several clinical sites and different ethnic groups were included to assess robustness of marker selection.
[6] All samples were tested with a reference methodology for MSI detection (Promega MSI analysis system).
[7] H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden,) and indel load, was whole-exome sequencing.
[8] The study method used the mutation landscape of 14 endometrial and colorectal MSI-High tumors that were previously characterized by whole-exome sequencing (Zhao et al., Elife 2014), and identified indels in homopolymers that recurrently affect MSI-High tumors (frequency up to 80% per tumor type). An additional 19 MSI-High tumors were positive for at least 2 out of 7 indels, while Microsatellite stable tumors were positive for none of them. The study further correlated the number of positive indels in all available MSI-H tumors (n=19+14) with mutation load.

mutational burden and total indel load. This provides us with a potential novel and easy-to-implement tool to predict tumor response to checkpoint blockade immunotherapy".

Herman Verrelst, CEO Biocartis, reacted: *"The selected ASCO studies once more demonstrate the innovative nature of the Idylla™ MSI Assay that we have under development. In our view, the unique features of this test are of great value to the pharmaceutical industry that needs rapid, reliable and easy MSI testing for a broad rollout of their immune-oncology treatments. Together we could enable more patients with MSI-High tumors to benefit from these promising immunotherapy treatments."*

The launch of Biocartis' fully automated Idylla™ MSI Assay (RUO[9]) is planned for H2 2018.

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More information:
Renate Degrave
Manager Corporate Communications & Investor Relations
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64
@Biocartis_ www.linkedin.com/Biocartis

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 fourteen 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

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.

[9] RUO = Research Use Only.