PRESS RELEASE 5 November 2019, 07:00 CET

Five Idylla™ Studies to be Published at 'Association for Molecular Pathology' Annual Meeting (US)

Mechelen, Belgium, 5 November 2019 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of five Idylla™ studies that were conducted by US key opinion leaders at the Annual Meeting of the Association for Molecular Pathology ('AMP'), a leading molecular diagnostics conference taking place this week between 7-9 November 2019 in Baltimore, Maryland (US). The respective Idylla™ studies showed a strong performance of Idylla™ assays (RUO[1]) compared to other methods including IHC[2] and NGS[3] in terms of concordance[4], ease of use, workflow automation and turnaround times. Furthermore, some studies researched Idylla™'s capability to analyze different sample types[5] and smaller sample quantities.

The published studies include the Idylla™ MSI, EGFR, KRAS and BRAF assays (RUO[1]) and can be summarized as follows:

- **Dartmouth – Hitchcock Medical Center (New Hampshire, US)[6]:** Study showed high concordance of the Idylla™ MSI Assay with an IHC[2] based method for the detection of MSI/dMMR status. The study also concluded that MSI testing on Idylla™ is a rapid and cost-effective alternative method to determine MSI status, without the need for a normal control tissue sample, with less than two minutes of hands-on time and 2.5 hour turnaround time.
- **Memorial Sloan Kettering Cancer Center (New York, US)[7]:** Study researched the rapid assessment of EGFR, KRAS and BRAF mutations and MSI status on Idylla™, using various tissue sample types[8], and demonstrated excellent reproducibility as well as 100% concordance with reference methods. Furthermore, a large sample set of > 1,100 samples tested with the Idylla™ EGFR Mutation Assay showed an invalid rate of only 1% as well as a significantly reduced turnaround time of 1-3 days compared to NGS-based assays averaging between 9 days and 3 weeks. Finally, concurrent testing with NGS on 520 samples of the aforementioned sample set showed a concordance of 98%.
- **University of Alabama (Birmingham, Alabama, US)[9]:** Study concluded that the Idylla™ KRAS Mutation Assay could be an alternative method to rescue samples that appeared inadequate for a larger NGS-based panel, with the added benefit of a fast two-hour turnaround time[10].
- **University of Colorado (Aurora, Colorado, US)[11]:** Study showed that the Idylla™ EGFR and BRAF Mutation Assays demonstrate high sensitivity and specificity for many variants of pre-extracted nucleic acid[12] from FFPE[13].
- **University of New Mexico (Albuquerque, New Mexico, US)[14]:** Study showed that the Idylla™ BRAF Mutation Assay may represent a useful method to evaluate FFPE sections containing lower than normal amounts of tissue[15].

Abstracts of the above mentioned studies can be found here.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*Idylla™ studies continue to be a key driver in the further market adoption of the Idylla™ platform. We are proud to see so many publications published at AMP by leading US key opinion leaders on the performance of Idylla™ compared to other methods such as IHC and NGS. It is great to see that once again the conclusions of these studies underline Idylla™'s unique features: providing highly accurate results faster and easier, even with minimal sample quality or on samples that failed on other testing methods."*

[1] Research Use Only, not for use in diagnostic procedures
[2] Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy.
[3] Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 21 October 2019.
[4] We refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5.
[5] Incl. (un)extracted FFPE tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries.
[6] G.J. Tsongalis et al., "Evaluation of a Cartridge-Based Assay to Assess Microsatellite Instability from FFPE Colorectal Cancer Tissues".
[7] K. Nafa et al., "Validation and Implementation of Ultra-rapid Mutation and MSI Assessment Using the Idylla Platform".
[8] Performed on 275 samples (175 positives: 50 EGFR, 57 KRAS, 68 BRAF; and 48 negatives: 12 EGFR, 17 KRAS, 19 BRAF; 25 MSI-H, 27 MSS) that were tested in the validation studies. Concordant results were obtained for all samples across all specimen types compared to reference methods of similar sensitivity with excellent reproducibility. Samples included both extracted and unextracted formalin-fixed, paraffin-embedded (FFPE) tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries. Note: Assessment of various sample types with or without previous extraction is possible but must be validated independently to establish adequate tissue input and performance requirements.
[9] Q. Wei et al., "Validation of Extracted DNA for Detection of KRAS Mutations with Idylla PCR-Based Molecular Diagnostic Assay: Can We Rescue Small Samples?"
[10] Results showed 100% concordance with previous NGS results when 10 ng is used.
[11] K.D. Davies et al., "Validation of the BioCartis Idylla Platform Using Extracted Nucleic Acid as Input."
[12] Idylla™ is designed to minimize hands-on time by fully automating all wet-bench steps. Nucleic acid extraction is built into the workflow such that tissue samples can be directly input into assay cartridges. However, pre-extracted nucleic acid may also be used as the input material.
[13] FFPE = Formalin-fixed, paraffin-embedded. When 75 ng DNA is directly input to the cartridges.
[14] Judd et al., "Evaluation of the Performance of the Biocartis Idylla BRAF Cartridge with Low DNA Input".
[15] The DNA was introduced directly into the BRAF cartridges in amounts ranging from 5 to 20 ng of DNA to simulate low overall sample cell content.

On 6 November 2019, Biocartis will host a workshop at the AMP 2019 conference that focuses on various features of the Idylla™ platform, with leading speakers from the Memorial Sloan Kettering Cancer Center (Dr. Maria Arcila, MD, Laboratory Director, Diagnostic Molecular Pathology Laboratory), Geisinger Medical Laboratories (Dr. Yi Ding, MD, PhD, System and Core Laboratory Director of Molecular Diagnostics) and the Dartmouth–Hitchcock Medical Center (Dr. Gregory J. Tsongalis, Vice Chair of Research, Department of Pathology and Laboratory Medicine).

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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 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.