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Eight Idylla™ Performance Studies to be Presented at the Association for Molecular Pathology Conference in the US

Mechelen, Belgium, 1 November 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of eight Idylla™ performance study abstracts at the Association for Molecular Pathology ('AMP') conference, the leading meeting of professionals in the field of molecular diagnostics taking place between 1-3 November 2018 in San Antonio, Texas (US). The studies are performed by renowned US oncology key opinion leaders from the Memorial Sloan Kettering Cancer Center (New York), Dartmouth–Hitchcock Medical Center (New Hampshire), AstraZeneca and the University of Alabama. All abstracts again highlight excellent Idylla™ performance, showing high concordance with current testing methods in combination with the unique features of the Idylla™ platform, being its ease of use, fully automated workflow and short turnaround times.

The eight Idylla™ abstracts relate to performance studies of the Idylla™ MSI Mutation Assay (RUO[1]), the Idylla™ EGFR Mutation Assay (RUO), the Idylla™ KRAS Mutation Assay (RUO) and the Idylla™ BRAF Mutation Assay (RUO), led by various US key opinion leaders from:

- The Memorial Sloan Kettering Cancer Center (New York, US):
  - K. Nafa et al., Memorial Sloan Ketting Cancer Center, "Rapid Assessment of Microsatellite Instability Status using the Idylla™ MSI Test"
  - M.E. Arcila et al., Memorial Sloan Ketting Cancer Center, "Ultra-Rapid EGFR Mutation Assessment in Lung Adenocarcinoma without Prior DNA Extraction"
- The Dartmouth – Hitchcock Medical Center (New Hampshire, US):
  - C.M. Nicka et al., Dartmouth-Hitchcock Medical Center, "Detection of Microsatellite Instability in Endometrial Carcinoma Using the Novel Idylla™ MSI Assay"
  - N.S. Maloney et al., Dartmouth-Hitchcock Medical Center, "Biocartis Idylla™ Cartridge-based Microsatellite Instability Assay Shows High Concordance with Immunohistochemical Analysis for Mismatch Repair Status in Colorectal Cancer"
  - M. Rabie Al-Turkmani et al., Dartmouth-Hitchcock Medical Center, "Stat EGFR Mutation Detection in Fresh Lung Cancer Tissue Specimens Using Touch Preparation and the Idylla™ System"
  - M. Rabie Al-Turkmani et al., Dartmouth-Hitchcock Medical Center, "Rapid EGFR Mutation Testing in Lung Cancer Tissue Samples Using a Fully Automated System and Single-use Cartridge"
- AstraZeneca:
  - M. Kohlman et al., AstraZeneca, on the comparison of the Idylla™ EGFR Mutation Assay[1,2] based on 79 clinical FFPE[3] tissue samples
- The University of Alabama:
  - D. Morlote et al, "Validation of FFPE Tissue Punches for Detection of KRAS and BRAF Mutations with the Idylla™ PCR-based Molecular Diagnostics Assay"

One of the Dartmouth-Hitchcock Medical Center abstracts is an EGFR testing study using limited fresh lung cancer tissue touch-preparation specimens[4] on Idylla™. Results showed complete concordance with NGS[5] testing on all samples but with a total time-to-result[6] of less than three hours compared to ± 5.5 days for NGS. This shows that with the ease of use and sensitivity of Idylla™, touch preparation samples may be used to rapidly detect actionable mutations while preserving tumor tissue for subsequent (NGS) processing and analysis. This approach provides fast turnaround times, which could open doors for timely management decisions for time-sensitive cancer cases while awaiting more comprehensive tumor genome profiling, such as with NGS.

[1] Research Use Only, not for use in diagnostic procedures.
[2] The study abstract can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
[3] Formalin fixed, paraffin embedded.
[4] Using touch preparation. Touch preparation samples were obtained from fifteen lung cancer tissue specimens in the pathology gross room shortly after resection. This involved making a single incision into the tumor body at room temperature using a scalpel blade and touching one 10 mm filter paper on each of the two sides of the inner tumor surface and holding it in position for approximately 3 seconds. The two filter papers were placed in an Idylla™ EGFR Mutation Assay cartridge (Research Use Only) and the cartridge was subsequently placed in the Idylla™ instrument for automated EGFR mutation analysis. The tumor tissue specimen was subsequently processed using standard pathology protocols for fixation, embedding and sectioning. Idylla™ results were compared with those obtained by subsequent somatic mutation analysis by next-generation sequencing (NGS) using the Ion AmpliSeq 50-gene Cancer Hotspot Panel v2 (Thermo Fisher Scientific).
[5] Next Generation Sequencing.
[6] Including analysis time, for all Idylla™ samples.

Another innovative study abstract[7] from the Memorial Sloan Kettering Cancer Center, one of the leading cancer centers in the US, used the Idylla™ MSI Assay (RUO) to determine MSI[8] status. It showed overall high concordance of 96% compared to previously determined MSI status[9] with large-panel targeted NGS data. The study indicates that the Idylla™ MSI Assay (RUO) offers a simple and fully automated solution to determine MSI status, providing rapid results that are highly concordant with other MSI testing approaches.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*We are very pleased with these eight studies conducted by key opinion leaders in the US who are using our Idylla™ products. These studies once again underline Idylla™'s unique positioning, providing results faster and easier than existing testing methods without compromising on performance. As such, these studies could be an important driver in the further adoption of Idylla™ in the US market.*"

Biocartis organized a workshop with speakers from the Memorial Sloan Kettering Cancer Center during the AMP conference in San Antonio (Texas, US) on 31 October 2018, highlighting the value of the Idylla™ EGFR, BRAF and MSI Assays[7]. For more information on the workshop, see the Biocartis website. The eight Idylla™ performance abstracts can be found here.

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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 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_.

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Forward-looking statements

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[7] K. Nafa et al., Memorial Sloan Ketting Cancer Center, "*Rapid Assessment of Microsatellite Instability Status using the Idylla™ MSI Test*", first published at AMP 2018, 1-3 November 2018, San Antonio (Texas, US).
[8] 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.
[9] Based on MSIsensor Score from large-panel targeted NGS data generated by MSK-IMPACT, MSI-PCR (Promega) and/or MMR IHC. The Idylla™ MSI Assay is Research Use Only, not for use in diagnostic procedures.