PRESS RELEASE 16 November 2020, 17:40 CET

Biocartis Announces Ten Idylla™ Studies to be Published at Virtual AMP (US) Annual Meeting

Mechelen, Belgium, 16 November 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of ten performance studies of its fully-automated molecular diagnostics Idylla™ platform at the annual meeting of the 'Association for Molecular Pathology' (AMP), a leading molecular diagnostics conference taking place virtually this year between 16-20 November 2020. The respective Idylla™ studies once again highlight the strengths of the Idylla™ platform and assays[1] in terms of performance, ease of use and turnaround time, as well as Idylla™'s capacity to overcome the obstacles of working with small amounts of sample, which represents a major challenge for many current molecular testing methods in a variety of different cancer types. Furthermore, three studies discuss new Biocartis assays in the area of infectious disease: the Idylla™ SARS-CoV-2 Assay and the SeptiCyte® RAPID on Idylla™.

The published oncology studies include the Idylla™ MSI, EGFR, ctEGFR, KRAS and ctKRAS Mutation Assays:

- The Memorial Sloan Kettering Cancer Center (New York, US) study[2] evaluated the performance of the Idylla™ MSI Assay across different tumor types (pan-cancer) including endometrial, colorectal, prostate, small bowel and breast cancer. Data presented showed equivalency to Immunohistochemistry (IHC)[3] and a greater sensitivity compared to MSK-IMPACT™, a Next Generation Sequencing (NGS) test, where the Idylla™ MSI Assay provided definitive results for numerous indeterminate cases.
- The University of Alabama at Birmingham (Birmingham, Alabama, US) study[4] showed 100% agreement between the Idylla™ MSI Assay and IHC using prostatectomy specimens and describes the Idylla™ MSI Assay as a reliable option for MSI testing in high-grade prostate cancer.
- The Dartmouth-Hitchcock Medical Center (New Hampshire, US) study[5] showed the feasibility of the Idylla™ MSI Assay to identify Lynch Syndrome[6] using colorectal adenomas.
- Two Massachusetts General Hospital (Boston, Massachusetts, US) studies showed how rapid testing with Idylla™ can complement comprehensive PCR/NGS[7] workflows, based on testing with the Idylla™ EGFR Mutation Assay and the Idylla™ ctKRAS Mutation Assay. Both studies show a reduction of the turnaround time with Idylla™ testing by approximately 50% or more, next to its ease of use and usefulness to provide for results when NGS fails[8].
- Another University of Alabama at Birmingham (Birmingham, Alabama, US) study[9] evaluated the performance of the Idylla™ KRAS Mutation Assay using de-stained cytology smears of lung non-small cell carcinoma (NSCLC) cases as an alternative source to rescue limited quantity samples. Comparison with previous NGS results showed 100% concordance.
- The Dartmouth-Hitchcock Medical Center (New Hampshire, US) study[10] evaluated the Idylla™ ctEGFR Mutation Assay on samples with DNA concentrations insufficient for NGS. Results showed a majority of samples successfully tested at a concentration of less than 40 ng DNA.

In addition, three studies discuss new Biocartis products in the area of infectious disease:

- The Dartmouth-Hitchcock Medical Center (New Hampshire, US) study[11] evaluated the Idylla™ SARS-CoV-2 Assay showing 100% concordance with their reference method.
- Biocartis' partner Immunexpress will present two abstracts[12] demonstrating that the new SeptiCyte® RAPID on Idylla™ correlates strongly with Immunexpress' existing SeptiCyte® LAB test, is reproducible, and can be used not only to differentiate patients with bacterial and viral, but also candida sepsis[13] from clinical controls.

[1] All studies were performed with Idylla™ RUO assays, research use only, not for use in diagnostic procedures
[2] ST41. Rapid Assessment of Microsatellite Instability across a Spectrum of Tumor Types Using the Idylla System, Momeni-Boroujeni1, M. Arcila2, D. Ferguson2, U. Patel2, R. Chan2, J. Barbee2, A. Zehir2, J. Hechtman2, M. Ladanyi2, K. Nafa2 1Brigham and Women's Hospital, Boston, MA; 2Memorial Sloan Kettering Cancer Center, New York, NY
[3] Immunohistochemistry is a laboratory method that uses antibodies to check for certain antigens (markers) in a sample of tissue. It's used to help diagnose diseases, such as cancer. It may also be used to help tell the difference between different types of cancer. Source: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunohistochemistry, last consulted on 12 November 2020
[4] ST06. Assessment of Microsatellite Instability on a Multi-Racial Cohort of High Grade Prostate Cancer Using Idylla MSI Test, M. Rodriguez Pena, S. Harada, A. Mackinnon, G. Netto, University of Alabama at Birmingham, Birmingham, AL
[5] ST60. Microsatellite Instability Testing for Lynch Syndrome Screening in Colorectal Adenomas, Javanbakht, L. Tafe, G. Tsongalis, E. Bradley, K. Godwin, D. Green, W. Keegan, B. Ren Dartmouth-Hitchcock Medical Center, Lebanon, NH
[6] Lynch Syndrome, also known as hereditary non-polyposis colorectal cancer (HNPCC), is a type of inherited cancer syndrome associated with a genetic predisposition to different cancer types. This means people with Lynch syndrome have a higher risk of certain types of cancer. Source: cancer.net, last consulted in 12 November 2020
[7] PCR = Polymerase Chain Reaction. NGS = Next Generation Sequencing
[8] The first study (ST40. Rapid qPCR Testing in the NGS Era Enables Same-Day Resulting of EGFR Mutant NSCLC, H. Marble, N. Georgantas, J. Lennerz Massachusetts General Hospital, Boston, MA) shows how replacing their current rapid PCR/EC assay with the Idylla™ EGFR Mutation Assay provides more comprehensive mutation coverage and can reduce the overall turnaround time by ~50%. Idylla™ delivers results on the same day as tumor sampling in most cases and enables targeted EGFR profiling of even scant tumor samples. Their second study (ST24. Benefits of Rapid Genotyping of KRAS Mutations versus NGS in Pancreatic Cyst Fluids; H. Marble, A. Farahani, N. Georgantas, J. Lennerz Massachusetts General Hospital, Boston, MA) demonstrates how rapid KRAS genotyping of pancreatic cysts with the Idylla™ ctKRAS Mutation Assay can be used to complement NGS-based profiling of pancreatic cancer. Idylla™ enables sample to result in 2.5 hours versus 10 to 14 days for NGS; is easy to use; and can provide results when NGS fails
[9] ST08. De-stained Cytology Smears Can Be Used for Detection of KRAS Mutations Using the Biocartis Idylla PCR-Based Molecular Diagnostic Assay, Q. Wei, S. Harada, I. Eltoum, G. DeFrank, A. Mackinnon, University of Alabama at Birmingham, Birmingham, AL
[10] TT25. Evaluation of the Biocartis Idylla ctEGFR Mutation Assay on Samples with DNA Concentrations Insufficient for Next-Generation Sequencing (NGS), W. Keegan, L. Tafe, E. Bradley, D. Green, G. Tsongalis Dartmouth-Hitchcock Medical Center, Lebanon, NH
[11] ID42. Evaluation of a Sample-to-Answer Cartridge-Based SARS-CoV-2 Assay, J. Lefferts, D. Green, G. Tsongalis, Dartmouth-Hitchcock Medical Center, Lebanon, NH
[12] ID02. Comparison of a Cartridge-Based Host Gene Expression Test to a Manual Method for Use in the Diagnosis of Sepsis, S. Cermelli1, K. Heath2, I. Keuleers3, G. Knox2, B. Lopansri4, J. McCleave5,M. Oethinger2, P. Sillekens3, W. Sinclair5, S. Thompson2, T. Vanhoey3 1IMMUNEXPRESS, Seattle, WA; 2 Providence Oregon Regional Laboratory, Portland, OR; 3Biocartis, Mechelen, Belgium; 4Intermountain Healthcare, Murray, UT; 5Intermountain Healthcare Laboratory Services, Murray, UT.; ID10. In silico Performance of a Rapid Sepsis Test in Patients with Candidemia, SSD. Sampson1, J. Butler2, H. Peters Sengers2; 1Immunexpress, Seattle, WA; 2 Academic Medical Centre, University of Amsterdam, Amsterdam, Netherlands
[13] In addition to bacteria, fungi—mainly Candida albicans and other Candida spp. —can cause sepsis and this entity has increased over the last decades, now causing significant impact and health care-associated costs. In addition, fungal sepsis is associated with a higher mortality than bacterial sepsis. Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4601378/, last consulted on 12 November 2020

Abstracts of the studies are published in the November 2020 issue of the Journal of Molecular Diagnostics.

Herman Verrelst, Chief Executive Officer of Biocartis, commented*: "We are proud of so many Idylla™ studies and abstracts being published at the renowned AMP conference this year. Having strong Idylla™ data published by leading US key opinion leaders, this time also on our newest infectious disease assays, continues to be a key driver in the further market adoption of the Idylla™ platform. We are pleased to once again see strong performance of our Idylla™ assays[1] compared to other methods such as IHC and NGS, combined with Idylla™'s rapid results reporting, ease of use and minimal sample requirements, even for samples that failed on other testing methods."*

Biocartis will also host a corporate workshop led by Dr. Maria E. Arcila, MD, Director of the Diagnostic Molecular Pathology Laboratory at Memorial Sloan Kettering Cancer Center (New York, US). Biocartis' partner Immunexpress will host a recorded workshop on the SeptiCyte® RAPID on Idylla™ led by Roy Davis, M.D., Ph.D., MHA, Chief Medical Officer at Immunexpress. For more info, go to the Biocartis events website.

--- END ---

More information:
Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
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 is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.