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Biocartis announces six Idylla™ abstracts to be presented at AMP 2024 Annual Meeting

Mechelen, Belgium, 23 October 2024 – Biocartis NV ("Biocartis"), an innovative molecular diagnostics company, is pleased to announce that six abstracts highlighting the benefits of Idylla™ will be presented at the Association for Molecular Pathology (AMP) Annual Meeting, taking place November 19th to November 23rd, 2024 in Vancouver, Canada. In addition, Biocartis will host a free corporate workshop.

Six Idylla™ abstracts from renowned institutions will be presented at this year's AMP conference, showcasing the strong collaborations Biocartis has built with leading research and academic partners.

1. **Performance Assessment and Clinical Validation of the Idylla™ IDH1-2 Mutation Assay Kit in Rapid Detection of IDH Mutations in Acute Myeloid Leukemia**
   Ashutosh Vashisht, Ashis K Mondal, Lora Walczak, Vishakha Vashisht, Shubha Sharma, Pankaj Ahluwalia, Jana Woodall, Harmanpreet Singh, Ravindra Kolhe - Department of Pathology, Medical College of Georgia, Augusta University, GA, USA.

By using 36 samples from 18 unique AML cases, the authors were able to demonstrate perfect concordance (100%) of the Idylla™ IDH1-2 Mutation Assay Kit with NGS. Directly using bone marrow aspirate in the Cartridge significantly reduced turnaround time, making this technique an ideal solution for developing assays for AML diagnosis, prognosis, and treatment evaluation.

2. **The Idylla™ Platform Enables Rapid and Accurate EGFR Mutation Assessment in NSCLC with Minimal Sample Input**
   Katherine Drews-Elger, Rodrigo Santoscoy-Valencia, Catherine Garcia-Serje, Silvia Gonzalez-Leiva, Mayra Rodriguez, Orlando Bracho-Rincon, and Roberto Ruiz-Cordero - Department of Pathology and Laboratory Medicine, University of Miami, Miami, FL - Jackson Memorial Hospital, Miami, FL - Clinical OncoMolecular Lab, Department of Pathology and Laboratory Medicine, University of Miami, Miami, FL.

This new prospective study demonstrated how the Idylla™ EGFR Mutation Assay offered rapid and accurate detection of EGFR mutations in non-small cell lung cancer (NSCLC), with 95% concordance with NGS. The Assay successfully identified mutations in cases where NGS could not be performed (10% of the cohort) and reduced turnaround time from 12.1 to 1.7 days. With minimal sample requirements and hands-on time, Idylla™ provided a faster option for obtaining EGFR mutation status in NSCLC.

3. **Re-verification and Report Ruling Revision of NTRK Fusion Results of Idylla™ GeneFusion Assay after Manufacturer Algorithm Update**
   Patricia Caffes, Gang Zheng M.D. Ph.D., Ying-Chun Lo M.D. Ph.D. - Division of Laboratory Genetics and Genomics, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN - Division of Anatomic Pathology, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN.

This recent re-verification study of the Idylla™ GeneFusion Assay demonstrated improved sensitivity for detecting NTRK2 fusions, due to a software update. Although sensitivity for NTRK3 decreased slightly, updates to the laboratory's standard operating procedure have enhanced accuracy by requiring confirmation testing for certain equivocal results. The study showed no changes to the detection of ALK, ROS1, RET, and MET fusions, maintaining 100% sensitivity and specificity.

4. **Rapid Determination of IDH1 and IDH2 Mutation Status in AML and Glioma Using Microfluidic Detection System**
   Catalina Esguerra, Anthony Magliocco - Protean BioDiagnostics

This study showed 97% accuracy, 100% sensitivity and 95% specificity for detecting IDH1 and IDH2 mutations in glioma and AML samples with the Idylla™ IDH1-2 Mutation Assay Kit. The Assay delivered rapid results within 95 minutes, with only one discordant case under investigation, potentially due to a higher sensitivity than the reference test. The Idylla™ System was praised for its ease of use and reliability, making it a valuable tool for determining IDH mutation status in various malignancies.

5. **The Idylla™ POLE Mutation Assay, a New Tool for Direct Mutation Detection from FFPE Tissue**
   Sofie Metsu - Biocartis

Based on a literature review, the diagnostic sensitivity of the (under development) Idylla™ POLE Mutation Assay for detecting POLE mutations with evidence to support clinical utility, was 98% in endometrial cancer and 90% colorectal cancer. The new assay is currently undergoing evaluation at multiple selected sites across Europe and the US, using clinical endometrial carcinoma FFPE specimens. The conclusive results will be shared at the AMP conference.

6. **Same-Day Molecular Testing Results from Cytology Specimens: The Next Frontier of the Rapid On-site Evaluation?**
   Dr. Gloria Sura - Cytology, MDACC

This MDACC study demonstrated the feasibility of Idylla™ for rapid and accurate molecular testing of NSCLC and thyroid cancer biomarkers from cytology samples. Results were available in 2-3 hours, with high accuracy across KRAS, EGFR, BRAF and GeneFusion Assays, showing concordance rates of 94-100%.

The Biocartis corporate workshop will take place on November 20th, 2024 at 3 PM PST and is focused on optimizing Fine Needle Aspiration (FNA) workflows using the Idylla™ Platform. Gloria Sura, MD (MD Anderson Cancer Center) will present a comprehensive feasibility and performance study showcasing the rapid assessment of EGFR, KRAS, BRAF and GeneFusion in cytopathology. Dr. Sura will highlight the integration of cytology and small biopsy specimens, particularly in lung and thyroid cancers, within a large cancer center.

W. Michael Korn, M.D., Chief Medical and Scientific Officer of Biocartis, commented: *"The research results that will be presented at the AMP Annual Meeting, highlight our commitment to expanding rapid and high-quality testing options for patients with hematological and solid malignancies. Our Idylla™ System allows for the analysis of small biological samples, including cytological specimens, providing healthcare providers with critical information for timely treatment decisions within hours."*

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More information:

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About Biocartis

With its revolutionary and proprietary Idylla™ Platform, Biocartis aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The Idylla™ Platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. Idylla™'s continuously expanding menu of

molecular diagnostic tests addresses key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung, breast, thyroid, brain, blood and liver cancer. More information: www.biocartis.com. Follow us on X (Twitter): @Biocartis.