New Study Led by Memorial Sloan Kettering Cancer Center (NY, US) Shows Idylla™ GeneFusion Assay Enables More Rapid Screening of Targetable Fusions Compared to Routine Methods

• Therapeutically actionable gene fusions drive approximately 10% of non-small-cell lung cancers1
• Current molecular methods including Next Generation Sequencing (NGS) are complex with long turnaround times
• Study2 demonstrates the Idylla™ GeneFusion Assay (RUO3) enables more rapid screening of targetable fusions compared to routine methods

Mechelen, Belgium, 4 May 2022 – Biocartis Group NV (the ‘Company’ or ‘Biocartis’), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a new study in the *Journal of Molecular Diagnostics* on the *Idylla™ GeneFusion Assay* (RUO) for rapid detection of targetable fusions involving ALK, ROS1, RET, and NTRK1/2/3 and MET exon 14 skipping mutations. The study concluded: “The assay enables rapid screening for clinically actionable kinase alterations with quicker turnaround and lower tissue requirements compared to immunohistochemistry and molecular methods, while also circumventing the infrastructure dependencies associated with Next Generation Sequencing (NGS) and fluorescence in situ hybridization”. The study was performed by Memorial Sloan Kettering Cancer Center (NY, US), one of the largest private cancer centers in the world.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: “This study shows the Idylla™ GeneFusion Assay’s added value when rapid testing is needed, and highlights other benefits including the Assay’s low tissue requirements that still allow for further NGS testing in negative cases, and perhaps most importantly, the results are delivered in three hours due to the fully automated nature of the Assay, where other methods today often take several days to weeks.”

Therapeutically actionable gene fusions drive approximately 10% of non-small-cell lung cancers1 (NSCLC). Up to 40% of rearrangement-driven lung cancers are diagnosed at an advanced stage (III to IV)4, however tyrosine kinase inhibitor therapy typically induces rapid and profound clinical improvement5. As such, timely recognition of these alterations is critical in the clinic. Current methods to detect kinase fusions such as fluorescence *in situ* hybridization (FISH) or NGS can be complex to perform, require a large lab infrastructure, have long turnaround times and can be cumbersome when it comes to interpretation of the data. Although NGS has become the mainstay for high throughput therapeutic target search, most NGS assays have high tissue requirements, need turnaround times of 2 to 3 weeks and bring about underlying genomic and biologic complexities that can lead to false-negative gene fusion results.

The study analyzed 143 independent FFPE6 tumor samples. The study stated that “testing was successful in 142 (99%) cases”. Furthermore, the study stated that “the Idylla™ GeneFusion Assay demonstrated a sensitivity of 97% (28/29), 100% (31/31), 92% (22/24), 81% (22/27), and 100% (20/20) for ALK, RET, ROS1, and NTRK1/2/3 rearrangements and MET exon 14 skipping alterations, respectively, with 100% specificity for all.”

The fully automated *Idylla™ GeneFusion Assay* (RUO) detects ALK, ROS1, RET, NTRK1/2/3 rearrangements and MET exon 14 skipping in a single cartridge, with less than 2 minutes hands-on time and results available in approx. 180 minutes.

The CE-IVD version of the Idylla™ GeneFusion Panel is planned for end of H1 2022.

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2 M. Arcila et al., ‘Clinical Utility and Performance of an Ultrarapid Multiplex RNA-Based Assay for Detection of ALK, ROS1, RET, and NTRK1/2/3 Rearrangements and MET Exon 14 Skipping Alterations’, Published 14 April 2022, DOI: https://www.ncbi.nlm.nih.gov/pubmed/35291578
3 Research Use Only, not for use in diagnostic procedures.
6 Formalin-Fixed, Paraffin Embedded
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 COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

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