PRESS RELEASE

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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 cancers*[1]
- *Current molecular methods including Next Generation Sequencing (NGS) are complex with long turnaround times*
- *Study*[2] *demonstrates the Idylla™ GeneFusion Assay (RUO*[3]*) 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 cancers[1] (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 improvement[5]. 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 FFPE[6] 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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1 Lee SE, et al., 'Comprehensive analysis of RET and ROS1 rearrangement in lung adenocarcinoma', Mod Pathol 2015, 28:468e479; and Pan Y et al., : 'ALK, ROS1 and RET fusions in 1139 lung adenocarcinomas: a comprehensive study of common and fusion pattern-specific clinicopathologic, histologic and cytologic features', Lung Cancer 2014, 84:121e126
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.jmdjournal.org/article/S1525-1578(22)00080-0/fulltext
3 Research Use Only, not for use in diagnostic procedures
4 Kim H et al., 'A comprehensive comparative analysis of the histomorphological features of ALK-rearranged lung adenocarcinoma based on driver oncogene mutations: frequent expression of epithelial-mesenchymal transition markers than other genotype', PLoS One 2013, 8:e76999
5 Kitazawa S, et al., 'Successful use of extracorporeal membrane oxygenation for airway-obstructing lung adenocarcinoma', Thorac Cancer 2020, 11:3024e3028
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_.

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.