PRESS RELEASE 14 September 2020, 07:00 CEST

Large Prospective Lung Cancer Study To Be Presented at ESMO Congress Shows Idylla™ Reduces EGFR Mutation Testing Turnaround Time by More than a Week, Allowing Faster Patient Management Decisions

Mechelen, Belgium, 14 September 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that a large prospective lung cancer study[1], co-supported by AstraZeneca, a global science-led biopharmaceutical company (LON: AZN), has been selected to be presented at the renowned European Society for Medical Oncology ('ESMO') Virtual Congress taking place between 19-21 September 2020. Rapid and accurate EGFR mutation testing is essential to make informed treatment decisions[2] for patients with advanced non-small cell lung cancer (NSCLC), and the study concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions.

The FACILITATE study is a large, prospective, real-world data set study across 16 European sites[3] that was launched as part of the agreement between Biocartis and AstraZeneca[4], aimed at obtaining faster lung cancer molecular diagnostic biomarker results in Europe. Between January 2019 and July 2020 a large set of 1,370 advanced non-small cell lung cancer (NSCLC) patient samples were tested using the Idylla™ EGFR Mutation Test[5] (CE-IVD) and local reference methods[6] including targeted next-generation sequencing (NGS). Results showed a 97.6%[7] overall percentage agreement between Idylla™ and reference methods. Ninety percent of all samples were tested in less than 7 days using the Idylla™ technology, versus less than 21 days using the reference methods. This demonstrates that Idylla™ improves turnaround time, allowing for fast-track testing when required, complementary to slower existing laboratory processes and systems.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"A large study with a broad data set such as this one with our partner AstraZeneca, who is at the forefront of lung cancer treatment, shows once again how Idylla™ can make a significant improvement for patients. With Idylla™, a fully automated rapid EGFR mutation diagnostic workflow[8] becomes possible, decreasing testing turnaround time and allowing earlier patient management decisions, following diagnosis."*

Prof. Dr. Michael Hummel, Head of the Molecular Pathology Group, Institute of Pathology, Charite - Universitätsmedizin Berlin*: "Lung cancer often requires immediate and adequate treatment. Rapid detection of the vast majority of relevant EGFR mutations provides an excellent targeted treatment option avoiding chemotherapy. In our large real-world study it became very obvious that the Idylla™ system is able to support treatment decisions extremely fast and accurate, much faster than the in-house solutions applied."*

The abstract poster will be published during the poster sessions at the ESMO Virtual Congress taking place between 19-21 September 2020 and is available here. Other Idylla™ study abstracts selected for ESMO can bedownloaded from the ESMO website here. .

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1 Hummel M. et al, "*FACILITATE: a real-world multicentre prospective study investigating the utility of a rapid, fully automated RT-PCR assay vs reference methods (RM) for detecting epidermal growth factor receptor mutations (EGFRm) in NSCLC*", ESMO Virtual Congress 2020 (19-21 September 2020), first published online on 14 September 2020
2 Epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs) are indicated as first-line therapy for patients with EGFR-mutated (EGFRm) advanced or metastatic NSCLC, where the EGFR mutational status has been confirmed using a validated and approved test method
3 In Belgium, France, Germany and Italy. The study aimed to prospectively test 100 paraffin-embedded biopsy or cytology tissue samples with ≥10% neoplastic cells per site, from patients with advanced NSCLC
4 Announced on 29 November 2018, see here
5 The Idylla™ EGFR Mutation Test qualitatively detects all relevant EGFR mutations in exons 18–21 as recommended by the ESMO, ASCO, NCCN, and CAP/IASLC/AMP guidelines for determining the most appropriate patient management for patients with advanced NSCLC. In total, 51 mutations are detected
6 Reference methods were targeted next-generation sequencing (NGS, different gene panels), Cobas® EGFR Mutation Test, Sanger sequencing, Pyro sequencing, Sequenom mass spectrometry, Hybrid Capture, and Entrogen EGFR Mutation Analysis Kit
7 The 3% discordance observed was partially attributable to rarer mutations that Idylla™ is not designed to detect
8 Idylla™ EGFR Mutation Test is intended to aid in the assesment of mutational status of patients with lung cancer and to facilitate treatment decisions within a multidisciplinary team

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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. 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.