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New Idylla™ EGFR Study Shows Reduction of Time-to-Treatment by 48% for Lung Cancer Patients

Idylla™ EGFR Mutation Test (CE-IVD) leading to time-to-treatment on average 16.8 days faster than Next Generation Sequencing (NGS) for EGFR positive patients, as such showing Idylla™'s potential to improve strategic treatment decisions of patients with advanced non-small cell lung cancer

Mechelen, Belgium, **8 November 2022 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the recent publication of a new, large prospective study[1] demonstrating that the Idylla™ EGFR Mutation Test (CE-IVD[2]) leads to the significant reduction of the time-to-treatment by 48% or on average 16.8 days faster than NGS testing for EGFR positive patients. This shows Idylla™'s potential to improve strategic treatment decisions within a multidisciplinary team for patients with advanced non-small cell lung cancer (NSCLC).

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*Tailoring cancer treatments to individual patients is key, and require molecular diagnostic testing to help identify the specific biomarkers involved. Recent studies[3] among approximately 1,600 patients show that in many European countries, less than 50% of the patients undergo biomarker testing. This is due to, among other reasons, lack of diagnostic laboratory infrastructure which also hinders a broader uptake of more complex testing technologies such as NGS. Integrating decentralized, rapid and easy-to-use Idylla™ testing in routine use can help broaden access to biomarker testing and as such, improve patient treatment and outcomes. We are therefore very pleased with another study showing the significant impact of Idylla™ on time-to-treatment that is no less than 16.8 days faster than NGS for EGFR positive patients with advanced NSCLC.*"

The study was performed on 238 samples which were tested both using an NGS panel (Oncopanel) and the Idylla™ EGFR Mutation Test[4]. The study showed a concordance of 98.7% between the Idylla™ EGFR Mutation Test and the NGS panel. The lab turnaround time was faster for the Idylla™ EGFR Mutation Test by an average of 12.4 days. In the EGFR positive cohort, the Idylla™ EGFR Mutation Test led to a 48% reduction and on average 16.8 days faster turnaround time.

Furthermore, the study concludes that the Idylla™ EGFR Mutation Test could contribute to overall time and cost savings for patients if testing is implemented in a stepwise manner, where the Idylla™ EGFR Mutation Test and the PD-L1 IHC (Immunohistochemistry) test are performed first, and comprehensive yet more expensive NGS panel testing is only initiated in case of a negative Idylla™ EGFR Mutation Test. Such first-line use of Idylla™ EGFR Mutation Test is not only more cost-effective, but it also allows to obtain EGFR test results in the same time frame as the PD-L1 IHC test results, which is important as EGFR positivity may be a contra-indication for PD-1/PD-L1 therapy in NSCLC[5].

The impact of the rapid Idylla™ EGFR Mutation Test on turnaround times is in line with previous studies[6] published, concluding that Idylla™ testing early on may contribute to improving strategic treatment decisions in a multidisciplinary team for patients with NSCLC by the early screening of EGFR mutations.

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1 Banyi N, Alex D, Hughesman C, McNeil K, N Ionescu D, Ma C, Yip S, Melosky B. Improving Time-to-Treatment for Advanced Non-Small Cell Lung Cancer Patients through Faster Single Gene EGFR Testing Using the Idylla™ EGFR Testing Platform. Curr Oncol. 2022 Oct 18;29(10):7900-7911. doi: 10.3390/curroncol29100624. PMID: 36290901
2 The Idylla™ platform is cleared in the US under K163628. Idylla™ EGFR assay is for Research Use Only in the United States, not for use in diagnostic procedures. For more information, go to https://www.biocartis.com/en-US
3 Normanno N, Apostolidis K, Wolf A, Al Dieri R, Deans Z, Fairley J, Maas J, Martinez A, Moch H, Nielsen S, Pilz T, Rouleau E, Patton S, Williams V. Access and quality of biomarker testing for precision oncology in Europe. Eur J Cancer. 2022 Oct 1;176:70-77. doi: 10.1016/j.ejca.2022.09.005. Epub ahead of print. PMID: 36194905
4 For each patient, the time that the lab received the sample, the time taken to report the NGS and Idylla™ testing results, the time of first treatment and the final treatment regimen were taken into account
5 J. Mazieres et al. Immune checkpoint inhibitors for patients with advanced lung cancer and oncogenic driver alterations: results from the IMMUNOTARGET registry. Annals of Oncology 2019
6 Including Petiteau C, Robinet-Zimmermann G, Riot A, Dorbeau M, Richard N, Blanc-Fournier C, Bibeau F, Deshayes S, Bergot E, Gervais R, Levallet G. Contribution of the IdyllaTM System to Improving the Therapeutic Care of Patients with NSCLC through Early Screening of *EGFR* Mutations. Curr Oncol. 2021 Nov 3;28(6):4432-4445. doi: 10.3390/curroncol28060376. PMID: 34898548; PMCID: PMC8628756; Finall A, Davies G, Jones T, et al. J Clin Pathol Epub ahead of print. doi:10.1136/ jclinpath-2021-207987

About Biocartis

With its revolutionary and proprietary Idylla™ platform, Biocartis (Euronext Brussels: BCART) 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 address 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 and liver cancer, as well as for COVID-19, Flu, RSV and sepsis. For more information, visit www.biocartis.com or follow Biocartis on Twitter @Biocartis_ , Facebook or LinkedIn.

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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.