



PRESS RELEASE

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New Study Demonstrates Idylla™ EGFR Mutation Test (CE-IVD) Shortens Time to Patient Management Decisions for Patients with Non-Small Cell Lung Cancer

Mechelen, Belgium, 16 November 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a [new study](#)¹ that demonstrates that the [Idylla™ EGFR Mutation Test](#) (CE-IVD) running on Biocartis' molecular diagnostics Idylla™ platform improves patient management decisions for patients with non-small cell lung cancer (NSCLC) through the faster screening of EGFR mutations.

Nearly 85% of lung cancers are non-small cell lung cancers². EGFR or 'Epidermal Growth Factor Receptor' mutations are the second most common cancer driver mutation in NSCLC. EGFR testing is important for the detection of EGFR mutations which helps to determine whether someone with NSCLC may benefit from targeted therapy-based regimens in case of presence of EGFR mutations, or potentially from immunotherapy-based regimens in case of absence of EGFR mutations³. EGFR mutations are commonly assessed by using Next-Generation Sequencing (NGS). This is a more complex and time-consuming technology, leading to an average expected time-to-result of approx. 15 days, which delays informed patient management decisions for patients with NSCLC.

The Idylla™ EGFR Mutation Test is a fully automated test using a slice of formalin-fixed, paraffin embedded (FFPE) tissue material as sample input, requiring less than 2 minutes hands-on-time and generating results in about 150 minutes. Previous studies⁴ have already reported excellent concordance between the Idylla™ EGFR Mutation Test and other routine EGFR testing methods, including NGS. This new study however specifically investigated if the faster time-to-result of the Idylla™ EGFR Mutation Test could shorten the time to patient management decisions for patients with NSCLC, as compared to NGS.

The study compared EGFR mutations analysis between the Idylla™ platform using the Idylla™ EGFR Mutation Test, and NGS in 223 patients with NSCLC. Idylla™ demonstrated 96.4% overall agreement with NGS and did not generate any false positive results⁵. On average, EGFR results using Idylla™ became available 12.6 calendar days earlier compared to NGS. As a result, with Idylla™, the timeframe from tumor sampling to the initiation of treatment was 16.1 calendar days earlier compared to NGS. The study concluded that the Idylla™ platform contributes to improving patient management decisions for patients with NSCLC through the faster screening of EGFR mutations.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: " *This new publication clearly shows the high clinical value of our Idylla™ EGFR Mutation Test. The study demonstrates it is a sensitive and rapid solution for the detection of EGFR mutations with a significantly faster turnaround time compared to NGS. On average, with Idylla™, time to patient management decisions was shortened with two weeks compared to the use of NGS.* "

The study can be consulted on the website of 'Current Oncology' [here](#).

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1 Petiteau, C.; Robinet-Zimmermann, G.; Riot, A.; Dorbeau, M.; Richard, N.; Blanc-Fournier, C.; Bibeau, F.; Deshayes, S.; Bergot, E.; Gervais, R.; et al. Contribution of the Idylla™ System to Improving the Therapeutic Care of Patients with NSCLC through Early Screening of EGFR Mutations. *Curr. Oncol.* 2021, 28, 4432–4445. <https://doi.org/10.3390/curroncol28060376>, published 3 November 2021

2 Hutchinson, B.; Shroff, G.S.; Truong, M.T.; Ko, J.P. Spectrum of lung adenocarcinoma. *Semin. Ultrasound CT MRI* 2019, 40, 255–264

3 Hofman, P. EGFR Status Assessment for Better Care of Early Stage Non-Small Cell Lung Carcinoma: What Is Changing in the Daily Practice of Pathologists? *Cells* 2021, 10, 2157. <https://doi.org/10.3390/cells10082157>, first published on 21 Aug 2021

4 More info on www.biocartis.com/publications

5 The Idylla™ EGFR Mutation Test (CE-IVD) detected 20 of the 26 (77%) EGFR mutations that were detected using NGS. Regarding the seven missed EGFR mutations, five were not detected by design by the Idylla™ EGFR Mutation Test, one was assayed in a sample with insufficient neoplastic cell content for Idylla™, and the last was in a sample not validated by the Idylla™ EGFR Mutation Test (a bone metastasis)

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](https://twitter.com/Biocartis): @Biocartis_.

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