



PRESS RELEASE

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Biocartis Announces New Collaboration with AstraZeneca to Expand Availability of Idylla™ EGFR Biomarker Testing Among Patients with Lung Cancer

Approximately half of the patients with non-small cell lung cancer have tumor mutations that could inform a more targeted treatment approach, but many are not tested

Mechelen, Belgium, 4 May 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART) today announces to have signed a new agreement with AstraZeneca, a global science-led biopharmaceutical company (LSE/STO/Nasdaq: AZN), aimed at providing access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in Biocartis' European and global distributor markets¹ to support the identification of patients with EGFR mutations.

The new project expands the existing [master collaboration](#) agreement² between Biocartis and AstraZeneca, which was established to promote and bolster access to faster molecular diagnostic biomarker results. The project further builds on the conclusion of the large prospective lung cancer [FACILITATE](#) study³, co-sponsored by AstraZeneca and presented in September last year at the renowned ESMO Virtual Congress⁴. This study concluded that Idylla™ EGFR testing may add value in a clinical setting to generate actionable EGFR mutation results for non-small cell lung cancer (NSCLC) patients faster than routinely used methods⁵.

EGFR mutations are important biomarkers in NSCLC, occurring in 10-15% of all NSCLC patients in the US and the EU, and in 30-40% of all NSCLC patients in Asia⁶. The fully automated [Idylla™ EGFR Mutation Test \(CE-IVD\)](#) covers 51 mutations in a single cartridge using only 1 FFPE⁷ tissue section from metastatic NSCLC and showing a high concordance of >95% compared with reference methods⁸.

Commenting on the new agreement, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"AstraZeneca has become a trusted business partner to Biocartis and I'm very excited to see our partnership with them mature and grow. With this agreement, AstraZeneca will facilitate the onboarding of new Idylla™ users while improving access to the Idylla™ EGFR Mutation Test (CE-IVD). As such, we offer the possibility to improve biomarker identification in patients with non-small cell lung cancer and, in turn, inform tumor management boards to allow precise patient management decisions. This is important, since approximately half of the patients with non-small cell lung cancer have tumor mutations that could inform a more targeted treatment approach⁹, but many are not tested. Lowering barriers to testing by offering a fully automated diagnostic workflow can make a true difference in the area of lung cancer biomarker testing, which is one of our key strategic pillars in oncology."*

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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, as well as for SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on [Twitter](#): @Biocartis_.

¹ Excluding US, China and Japan
² Announced on 22 January 2020

³ 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

⁴ ESMO – European Society for Medical Oncology. The Virtual ESMO Congress took place in September 2020

⁵ Poster was presented at ESMO 2020, poster reference 1205P

⁶ Source: <https://www.astrazeneca.com/our-focus-areas/oncology/at-the-forefront-of-lung-cancer-treatment.html>, last consulted on 27 April 2021

⁷ FFPE = formalin fixed, paraffin embedded

⁸ De Luca et al. Journal of Clinical Pathology 2018;71:745-750

⁹ Tuma, Rabiya S. PHD More Than Half of NSCLC Patients Have Actionable Mutations, Lung Cancer Consortium Reports, Oncology Times: October 25, 2011 - Volume 33 - Issue 20 - p 31-32 doi: 10.1097/01.COT.0000407712.33021.9d

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