

Biocartis Receives EUR 1.2 million Grant for Development of Highly Innovative Idylla™ GeneFusion Assay

Mechelen, Belgium, 30 September 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that it has received a EUR 1.2 million grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the development of the highly innovative GeneFusion Assay on its easy, rapid molecular and fully automated diagnostics platform Idylla™.

The Idylla™ GeneFusion Assay will include a highly multiplexed panel of established and emerging biomarkers, and will be the first FFPE¹ RNA²-based assay on the Idylla™ platform. The Idylla™ GeneFusion Assay is expected to bring results in approx. 3 hours, with less than 2 minutes hands-on time. The VLAIO grant is intended to support the development of the GeneFusion Assay on the Idylla™ platform, and to support related research studies on different sample and tumor tissue types, including on lung cancer tissue.

Lung cancer is the most common cause of cancer-related deaths worldwide (27%) with 1.7 million deaths annually³. Clinical non-small cell lung cancer (NSCLC) guidelines⁴ recommend testing for amongst others EGFR mutations⁵. Today, gene fusions represent an increasingly important biomarker test category⁶. Although detected in a small portion of NSCLCs, testing for these gene fusions is important for the identification of patients who may benefit from different fusion gene targeted therapies, which show high response rates and long disease control upon treatment⁷. Current testing methods however are cumbersome because different technologies⁸ are needed to test all required biomarkers. Additionally, sample quantity and quality to perform all these tests are commonly suboptimal. Due to these complexities, time to results can be delayed, which can lead to inappropriate treatment decisions.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: “*We are very pleased to receive this VLAIO grant and support from the Flemish government for highly innovative projects such as our GeneFusion Assay project. In the area of lung cancer testing, there is a clear unmet diagnostic need for comprehensive and fast molecular testing solutions that are compatible with a limited amount of sample. Together with the existing Idylla™ EGFR Mutation Test (CE-IVD), a key test in our lung cancer menu, the Idylla™ GeneFusion Assay (RUO⁹) is expected to offer our customers-laboratories a comprehensive testing solution for molecular biomarkers in this area, without the need for different instruments, and covering the majority of clinical guideline-recommended biomarkers.*”

Biocartis expects to launch its Idylla™ GeneFusion Assay as a Research Use Only (RUO) assay in Q1 2021. Validation and release of an IVD version for use in NSCLC is also anticipated.

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¹ Formalin fixed, paraffin embedded

² Ribonucleic Acid. RNA is one of the three major biological macromolecules that are essential for all known forms of life (along with DNA and proteins)

³ Despite advances in early detection and treatment, most patients are diagnosed at an advanced stage and have a poor prognosis, with an overall 5-year survival rate of approx. 15%. Source: Kim E.S., Roy U.B., Ersek J.L., King J., Smith R.A., Martin N., Martins R., Moore A., Silvestri G.A., Jett J., 2019, Updates regarding biomarker testing for non-small cell lung cancer: considerations from the National Lung Cancer Roundtable

⁴ CAP/IASLC/AMP: College of American Pathologists/ International Association for the study of lung cancer/ Association for Molecular Pathology

⁵ And for ALK fusions, ROS1 fusions and BRAF mutations

⁶ One of the best-characterized examples is the fusion of EML4 and ALK genes, which is also the most prevalent fusion occurring in about 5% of NSCLCs

⁷ Villalobos P., Wistuba I.I., 2018, [Lung cancer biomarkers](https://www.cancer.org/cancer/lung-cancer/treating-non-small-cell/targeted-therapies.html). See also <https://www.cancer.org/cancer/lung-cancer/treating-non-small-cell/targeted-therapies.html>, last consulted on 24 September 2020. Peters et al, N Engl J Med 2017 377:829-838; Hong et al, Lancet Oncol 2020 21(4):531-540; Drilon et al N Engl J Med 2020; 383:813-824

⁸ Techniques used to detect NTRK gene fusions include DNA-based next-generation sequencing (NGS), RNA-based NGS, reverse-transcriptase PCR (RT-PCR), fluorescence in situ hybridisation (FISH), and immunohistochemistry (IHC). Source: OncologyPro, ESMO, see [here](#), last consulted on 23 September 2020

⁹ Not for use in diagnostic procedures

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

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