



PRESS RELEASE

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Biocartis Launches Idylla™ GeneFusion Assay as Rapid Lab Workflow Solution for Gene Fusion Testing

Mechelen, Belgium, 22 March 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of the highly innovative [Idylla™ GeneFusion Assay](#) (RUO¹). The Assay detects, in one single cartridge, a wide range of biomarkers covering all gene fusions considered to be relevant in cancer research. The Idylla™ GeneFusion Assay (RUO) is therefore expected to provide a much faster testing solution for laboratories, compared to other testing methods including Next-generation Sequencing (NGS) testing which often takes days or even weeks before results are available.

Gene fusions represent an important class of somatic alterations in cancer and have become important biomarkers for cancer diagnosis, prognosis and the selection of targeted therapies². The discovery and research for further understanding of fusion genes across multiple cancer types may provide more effective therapies in the future. Over the last 20 years, many gene fusions have been discovered in hematological cancers, solid tumors and sarcomas. Current gene fusion testing techniques are complex since these require a combination of different technologies³, often only available in different laboratories, to test all needed biomarkers. This also implies the need for sufficient sample quality and quantity which is difficult to obtain, especially for certain cancers such as lung cancer.

The Idylla™ GeneFusion Assay (RUO) includes a highly multiplexed panel of biomarkers and is the first FFPE⁴ RNA⁵-based assay on the Idylla™ platform. The Assay consolidates traditional testing workflows into one fully automated process providing objective information on ALK, ROS1, RET, NTRK1/2/3 fusions and MET exon 14 skipping, all in one cartridge, directly from 1-3 slices of FFPE tissue. Results are available within approx. 3 hours, with less than 2 minutes hands-on time. Preliminary data⁶ comparing the Idylla™ GeneFusion Assay (RUO) with today's frequently used technologies such as Immunohistochemistry, FISH or NGS, show excellent results of the Assay, with concordance up to 100%.

Commenting on the launch of the Idylla™ GeneFusion Assay, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"This Assay is long-awaited by many of our lab-customers who, from now on, will be able to test gene fusions in a very fast and simple manner. Thanks to a unique combination of two detection technologies, the Idylla™ GeneFusion Assay (RUO) contains all relevant gene fusion biomarkers in one single cartridge, allowing labs to rapidly integrate gene fusion testing in their workflows. The benefits of this Assay not only include its speed and simplicity, but it also requires limited sample input thereby saving valuable tissue specimens. This is often an issue in areas such as biomarker testing performed on lung tissue. With the addition of the Idylla™ GeneFusion Assay (RUO) to our test menu, we can from now on offer our lab-customers a comprehensive testing solution for molecular biomarkers in this area, without the need for different instruments, and covering the majority of recognized gene fusion biomarkers."*

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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 RUO – Research Use Only. The Idylla™ GeneFusion Assay is for Research Use Only, not for use in diagnostic procedures

² Stransky et al. The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014; Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015

³ 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 15 March 2021

⁴ Formalin fixed, paraffin embedded

⁵ 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)

⁶ The concordance study was performed on NSCLC (non-small cell lung cancer) and thyroid cancer samples with prototype cartridges but re-analyzed with final Idylla™ GeneFusion Assay (RUO) decision tree. Moreover, the Idylla™ GeneFusion Assay was able to generate accurate results in 29/32 inconclusive IHC and FISH results. Preliminary data can be found on <https://www.biocartis.com/en/meet-idylla/idylla-oncology-assays>

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