



BIOCARTIS ANNOUNCES THE LAUNCH OF THE FIRST ASSAY DEVELOPED WITH THE NEW IDYLLA™ FLEX TECHNOLOGY

Mechelen, Belgium, 9 February 2023 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of the Idylla™ IDH1-2 Mutation Assay Kit (RUO)¹ among selected customers. The assay is the first test developed with the new Idylla™ FLEX technology that separates the generic components of an Idylla™ test from the test-specific components. The Idylla™ IDH1-2 Mutation Assay Kit (RUO) will become globally available to customers during the second half of 2023.

The Idylla™ FLEX technology shortens the development time of new Idylla™ assays, allowing to bring them to the market much faster. The technology combines a generic Idylla™ cartridge, which can be mass-manufactured on Biocartis' high-throughput manufacturing line at low cost, with the test-specific components that are provided in a separate vial of which the content can be added into the generic Idylla™ cartridge by the user together with the sample. The Idylla™ FLEX technology will first be deployed for tests that use FFPE², peripheral blood mononuclear cells, bone marrow mononuclear cells, whole blood or extracted DNA as sample type. In a next step, it is intended to be deployed for tests that can use up to 4 ml of plasma as sample type.

In a next phase, the off-line customization of the Idylla™ cartridge could be deployed in the rapidly growing field of molecular surveillance, where patients are monitored with molecular tests. The Idylla™ FLEX technology is ideally suited for both tumor-informed (aka bespoke or personalized) as well as tumor-naïve panels, both of which have shown promise for molecular surveillance. Moreover, Idylla™ FLEX will be a major steppingstone to testing liquid biopsy samples, which is expected to account for the largest share within the vast market opportunity of molecular surveillance monitoring.

The Idylla™ IDH1-2 Mutation Assay Kit (RUO) is the first test developed using the Idylla™ FLEX technology. Mutations in the isocitrate dehydrogenase 1 (IDH1) and 2 (IDH2) genes are oncogenic drivers that are frequently found in a variety of human malignancies, including gliomas, acute myeloid leukemia, cholangiocarcinoma, chondrosarcoma and thyroid carcinoma³. The Idylla™ IDH1-2 Mutation Assay Kit (RUO) can detect 5 mutations in IDH1 and 10 mutations in IDH2, along with an integrated processing control. The turn-around-time is less than 2 hours from sample to result. The assay performance has been evaluated at multiple sites in both US and Europe. The assay will be further deployed across the Biocartis customer base and will also be made available for partnerships with pharmaceutical companies, clinical research organizations and reference labs conducting research.

Herman Verrelst, Chief Executive Officer of Biocartis, said: *"We already had a broad menu of tests in oncology, which we now expand with a rapid test for the detection of mutations in IDH1 and IDH2. This new test was highly requested throughout our customer base, especially in the US. The successful development of this first assay using the Idylla™ FLEX technology is a major achievement and will allow us to expand our menu of tests on Idylla™ much faster and tap into the growing field of liquid biopsy-based monitoring."* **Benoit Devogelaere, Chief Technology Officer of Biocartis, further complemented:** *"The new Idylla™ FLEX technology has the potential to be deployed across the entire spectrum of research in molecular surveillance, including treatment response monitoring, Molecular Residual Disease (MRD)⁴ and recurrence monitoring. Now that cancer treatment becomes increasingly personalized, we see multiple fields of application for the customization and even personalization offered by the Idylla™ FLEX technology, in particular for the frequent and repeated liquid biopsy-based testing of patients."*

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¹ Research Use Only

² Formalin fixed, paraffin embedded tissues are samples, typically from suspected tumors, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced very thinly

³ Han et al. 2020, IDH mutation in glioma: molecular mechanisms and potential therapeutic targets, British Journal of Cancer

⁴ Molecular Residual Disease is a small number of cancer cells left in the body after treatment. These cells have the potential to cause relapse in patients

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_](https://twitter.com/Biocartis_), [Facebook](https://www.facebook.com/Biocartis) or [LinkedIn](https://www.linkedin.com/company/biocartis).

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