Biocartis Announces Nine Idylla™ Studies to be Published at Upcoming AMP 2022 Annual Meeting

Mechelen, Belgium, 31 October 2022 — Biocartis Group NV (the ‘Company’ or ‘Biocartis’), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of nine performance study abstracts of its fully automated molecular diagnostics Idylla™ platform1 and assays2 at the annual meeting of the ‘Association for Molecular Pathology’ (AMP), a leading molecular diagnostics conference, taking place between 1-5 November in Phoenix, Arizona (US). The studies were performed by a variety of US laboratories and research institutes.

Among the studies published, four studies on the Idylla™ GeneFusion Assay2 highlighted the strengths of Idylla™ testing including high accuracy, ease-of-use and rapid time-to-results. Furthermore, one study performed with the new SeptiCyte RAPID® EDTA3 blood compatible cartridges4 (CE-IVD, not 510(k) cleared) on the Idylla™ platform, developed in collaboration with Immunexpress, concluded that the addition of the widely used EDTA blood tube as a validated sample type has the potential to greatly enhance the clinical utility of this new near-patient sepsis diagnostic.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: “These studies are great, especially the data published on the Idylla™ GeneFusion Assay which shows the benefit of Idylla™ biomarker testing versus testing on more complex and hence slower technologies such as Next Generation Sequencing, often used very early on in the biomarker testing process. With Idylla™, the time-to-result of diagnostic testing is decreased, demonstrating the suitability of Idylla™ testing for rapid broad molecular profiling.”

The other studies related to the use of the Idylla™ EGFR Assay, the Idylla™ MSI Assay and the Idylla™ NRAS-BRAF Assay. The Idylla™ study abstracts selected for AMP 2022 can be downloaded here.

During the AMP annual meeting, on 2 November 2022, Biocartis will host a free corporate workshop led by Dr. Rick Ledding, Histology Supervisor at Benefis Health Systems, sharing his experience on the implementation of the Idylla™ platform in his laboratory: “Bringing Rapid Molecular Testing In House: How to Set Up a No-Hassle Workflow.”

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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, Facebook or LinkedIn.

1 The Idylla™ platform is cleared in the US under K163628. Idylla™ EGFR, BRAF, KRAS, MSI, NRAS-BRAF, ctEGFR, ctBRAF, ctKRAS, ctNRAS-BRAF and GeneFusion assays are all for Research Use Only in the United States, not for use in diagnostic procedures. For more information, go to https://www.biocartis.com/en-US
2 Except for the study performed on the new SeptiCyte RAPID® EDTA blood compatible cartridges (CE-IVD, not 510(k) cleared), all studies were performed with Idylla™ RUO assays, for research use only, not for use in diagnostic procedures.
3 EDTA represents Ethylenediaminetetraacetic acid, which is the anticoagulant used for most hematology procedures (like identifying and counting blood cells, blood typing, etc.). Source: kmedical.com, last consulted on 28 Oct 2022
4 In addition to blood samples collected in PAXgene blood RNA tubes (per the manufacturer’s instructions), this test is now also able to process undiluted EDTA blood samples which are commonly used for most hematology procedures, with results available in about one hour.
Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

Forward-looking statements
Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company’s or, as appropriate, the Company directors’ or managements’ current expectations and projections concerning future events such as the Company’s results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person’s officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.