PRESS RELEASE

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Biocartis Announces Launch of its Rapid CE-marked IVD Idylla™ GeneFusion Panel for Fast Treatment Decisions in Lung Cancer

- *Idylla™ GeneFusion Panel available as rapid CE-marked IVD lung cancer testing solution for laboratories, with results within 180 minutes*
- *10% to 20% of advanced lung cancer patients don't receive the appropriate targeted therapy due to slow turnaround time of many current testing methods, leading to a delayed time-to-treatment*[1]

Mechelen, Belgium, **20 June 2022 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), announces the CE-marking of its fully automated Idylla™ GeneFusion Panel (CE-IVD). The Panel detects in one single cartridge ALK, ROS1, RET and METex14 skipping, a wide range of actionable targets relevant in non-small cell lung cancer (NSCLC). Designed for use in clinical laboratories, the Panel provides comprehensive testing results within 180 minutes, significantly faster than currently available testing methods which often take days or even weeks before results are available.

Lung cancer remains the leading cause of cancer deaths, with NSCLC being the most common type of lung cancer. The survival rate has increased over the past years due to the rapidly evolving treatment landscape for NSCLC. Gene fusions represent an important class of gene rearrangements and have become important in NSCLC, as they are linked to responses to certain targeted therapies. Their accurate and fast detection is critical to guide therapy choices, which is the reason why testing for gene rearrangements such as gene fusions is included in international NSCLC testing guidelines (including ESMO and NCCN).

However, comprehensive testing of actionable gene rearrangements in NSCLC is often complex and can require different technologies[2]. In order to test all needed biomarkers, laboratories usually have to use different instruments which are often not available within their own lab. Using different instruments also requires having enough biopsy samples of sufficient good quality, which can be difficult to obtain, especially in NSCLC patients.

Commenting on the launch of the Idylla™ GeneFusion Panel, Herman Verrelst, Chief Executive Officer of Biocartis, said: "*Turnaround time and time-to-treatment remains an important barrier to molecular testing. It has been demonstrated that 10% to 20% of advanced lung cancer patients do not receive the appropriate targeted therapy because biomarker results are not provided in a timely fashion*[1]*. With the CE-marked IVD of the Idylla™ GeneFusion Panel, laboratories will have a rapid actionable and in-house solution at their disposal which can be seamlessly integrated into virtually any laboratory workflow.*"

The Idylla™ GeneFusion Panel consolidates traditional testing workflows into one streamlined, fully-automated process which provides reliable information on ALK, ROS1, RET and METex14 skipping and delivers results within 180 minutes. Moreover, the Panel only requires a limited amount of sample, thereby saving valuable tissue specimens. The Idylla™ GeneFusion Panel demonstrated high concordance results in a clinical comparison study where ALK was compared with IHC, and ROS1, RET and METex14 skipping were compared with NGS[3].

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1 Finall et al. Integration of rapid PCR testing as an adjunct to NGS in diagnostic pathology services within the UK: evidence from a case series of non-squamous, non-small cell lung cancer (NSCLC) patients with follow-up? J Clin Pathol. 5 Jan 2022 Chu et al. Clinical Utility and Performance of an Ultrarapid Multiplex RNA-Based Assay for Detection of ALK, ROS1, RET, and NTRK1/2/3 Rearrangements and MET Exon 14 Skipping Alterations. J Mol Diagn. 2022 Apr

2 I.e. gene fusions and METex14 skipping. 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 2 June 2022

3 Data obtained from the clinical performance evaluation performed by Biocartis in view of the CE-marking. The clinical performance evaluation compared the Idylla™ GeneFusion Panel with IHC (VENTANA ALK (D5F3) Assay, Roche Diagnostics GmbH) for ALK; ROS1, RET and METex14 skipping were evaluated versus NGS (Oncomine™ Focus Assay, Thermo Fisher Scientific)

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 COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

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