



PRESS RELEASE

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## Biocartis Launches Liquid Biopsy Idylla™ ctEGFR Mutation Assay

**Mechelen, Belgium, 25 October 2019** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of the Idylla™ ctEGFR Mutation Assay (RUO<sup>1</sup>). This assay is the liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test (CE-IVD) and is further strengthening Biocartis' testing menu.

Obtaining samples for biomarker testing of sufficient quantity and quality is known to be a major challenge in several cancer types, including lung cancer. Solid tumor tissue samples might be too small, the tumor content might be too low or the tumor might be hard to reach. In these cases, liquid biopsy testing could provide for a solution. The Idylla™ ctEGFR Mutation Assay (RUO) is a liquid biopsy assay, performed on Biocartis' Idylla™ platform, which allows the detection of 49 EGFR mutations<sup>2</sup> directly from 2 ml of blood plasma and providing results within approximately 160 minutes.

During the recent European Society for Medical Oncology (ESMO) Congress<sup>3</sup>, a first performance study<sup>4</sup> was published on the prototype liquid biopsy Idylla™ ctEGFR Mutation Assay. The study included 64 non-small cell lung cancer (NSCLC) samples and concluded that the prototype Idylla™ ctEGFR Mutation Assay detected all mutations previously detected by the comparison method (Next-Generation Sequencing or NGS<sup>5</sup>). In 33 samples, NGS detected no mutation whereas the Idylla™ ctEGFR Mutation Assay detected eight additional mutations in this cohort<sup>6</sup>.

**Herman Verrelst, Chief Executive Officer at Biocartis, commented:** *"We are excited to further expand our Idylla™ menu of tests with the launch of the liquid biopsy ctEGFR Mutation Assay (RUO). Operating directly on only 2 ml of blood plasma, this assay provides our customers with the ease-of-use and speed of the Idylla™ platform and has great potential to provide solutions in cases where cancer tissue is not or not sufficiently available. This assay launch further strengthens our testing menu, which will be further complemented by the expected launch of our Idylla™ GeneFusion Panel next year, focused on the detection of different gene fusions that are currently recommended in the guidelines."*

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<sup>1</sup> RUO = Research Use Only, not for use in diagnostic procedures

<sup>2</sup> Including insertions and deletions in exon 18, 19, 20 and 21 in the EGFR gene

<sup>3</sup> 27 September - 1 October 2019 in Barcelona (Spain)

<sup>4</sup> Study conducted by Biocartis: Reijmans et al., ESMO 2019

<sup>5</sup> Sensitivity 2-5%

<sup>6</sup> Confirmed after retesting with the cobas EGFR Mutation Test v2. Of the 8 additional mutations, 7 mutations were detected in samples which were scored wild type by NGS

## **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 in oncology. This 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](http://www.biocartis.com). Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis\_.

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