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Biocartis Enters into Master Collaboration Agreement with AstraZeneca and Initiates EGFR Liquid Biopsy Study

Mechelen, Belgium, 22 January 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that it has entered into a master collaboration agreement with AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN). The master collaboration agreement enables the collaborative development and commercialization of Idylla™ based molecular tests in support of AstraZeneca's pharmaceutical products.

The announcement today marks a broadening of the existing partnership[1] between Biocartis and AstraZeneca that focused on demonstrating how the unique features of the Idylla™ platform can overcome the current complexity and long turnaround time of biomarker testing for lung cancer patients. The prospective study with the tissue-based Idylla™ EGFR Mutation Test (CE-IVD) under the existing partnership was initiated at more than a dozen sites in several European countries. In addition to the new master collaboration agreement, AstraZeneca and Biocartis have agreed to extend this ongoing study to additional countries within and outside Europe.

The scope of the new master collaboration agreement enables collaborative development and commercialization projects between Biocartis and AstraZeneca, such as but not limited to, companion diagnostic development projects that may cover any type of indication or biomarker. The first project to be initiated under the new agreement is a study focused on evaluating if liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO[2]) could provide further benefits to tissue-based EGFR molecular testing.

EGFR mutations are important biomarkers to be studied in Non-Small Cell Lung Cancer (NSCLC). AstraZeneca is marketing Tagrisso® (osimertinib) which is a leading lung cancer therapy approved for patients with metastatic NSCLC whose tumors have EGFR mutations. EGFR mutations occur in 10-15% of all NSCLC patients in the US and the EU and in 30-40% of all NSCLC patients in Asia[3]. The Idylla™ ctEGFR Mutation Assay (RUO[2]), launched in October 2019, is a liquid biopsy assay which allows the detection of 49 EGFR mutations directly from 2 ml of blood plasma and provides results within approximately 160 minutes.

Herman Verrelst, Chief Executive Officer of Biocartis, **commented**: *"We are very pleased to announce today that we are further developing our partnership with AstraZeneca by entering into a master collaboration agreement, with a first project focused on our newly launched liquid biopsy Idylla™ ctEGFR Mutation Assay[2]. Current EGFR molecular diagnostic testing is complex because obtaining high quality tissue samples is difficult, especially in NSCLC where tumors are often very small, leading often up to several weeks of waiting time[4] before results are available. Liquid biopsy EGFR testing with the Idylla™ ctEGFR Mutation Assay[2], operating directly from 2 ml of blood plasma, could overcome these challenges and delivers molecular EGFR mutation information faster and easier."*

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[1] Announced in a press release on 29 November 2018: "Biocartis and AstraZeneca Enter Into Agreement Aimed at Faster Lung Cancer Biomarker Results", available on www.biocartis.com
[2] Research Use Only, not for use in diagnostic procedures
[3] Source: https://www.astrazeneca.com/our-focus-areas/oncology/at-the-forefront-of-lung-cancer-treatment.html, last consulted on 14 January 2020
[4] Ibiayi Dagogo-Jack et al., 'Clinical Utility of Rapid EGFR Genotyping in Advanced Lung Cancer', JCO Precis Oncol. © 2018 by American Society of Clinical Oncology, published online on ascopubs.org/journal/po on 24 July 2018; Nafa et al (2019) Journal of Molecular Diagnostics; 21(6), Abstract #ST028

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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 in oncology. This area 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. Follow us on Twitter: @Biocartis_.

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.