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Biocartis Announces New Agreement with AstraZeneca for the Development and Marketing of a Companion Diagnostic Test for Tagrisso®

Mechelen, Belgium, **22 June 2022 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced that it has entered into an agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) aimed at the development and applicable pre-market notification or approval with the US FDA of a novel companion diagnostic[1] (CDx) test on Biocartis' molecular rapid and easy-to-use diagnostics Idylla™ platform, for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment.

Under the terms of the agreement, Biocartis and AstraZeneca will co-lead the development and applicable pre-market notification or approval of the Idylla™ EGFR CDx Assay intended to aid in identifying patients with non-small cell lung cancer (NSCLC) who may respond to treatment with Tagrisso®. In addition to FFPE[2] tissue, Biocartis will seek to validate the use of less invasive cytology samples such as fine needle aspirates[3] for use with the Idylla™ EGFR CDx Assay, to expand patient access to testing.

The new project expands the existing master collaboration agreement announced in January 2020 between Biocartis and AstraZeneca[4], aimed at boosting access to faster molecular diagnostic biomarker results with the rapid and easy-to-use Idylla™ EGFR testing products. The collaboration was supported by the large prospective lung cancer FACILITATE study, co-sponsored by AstraZeneca. This study concluded that Idylla™ EGFR testing may add value in a clinical setting to generate actionable EGFR mutation results for NSCLC patients faster than routinely used methods. In this respect, the newly signed agreement includes the investigational use of the Idylla™ EGFR CDx Assay to enroll patients in clinical trials at AstraZeneca.

AstraZeneca is marketing Tagrisso®, a leading lung cancer therapy approved for patients with resectable and locally advanced or metastatic NSCLC whose tumors have EGFR mutations. EGFR activating mutations are important biomarkers in NSCLC, occurring in 10-15% of all NSCLC patients in the US and the EU, and in 30-40% of all NSCLC patients in Asia[5].

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We are excited to move our collaboration with AstraZeneca to a next level with the development of a companion diagnostic test on Idylla™ that may enable faster and broader patient access to AstraZeneca's Tagrisso® treatment. Current EGFR molecular diagnostic testing remains a real challenge in the clinical practice. Obtaining high quality tissue samples is difficult and complex, especially in NSCLC where tumors are frequently very small, often leading up to several weeks of waiting time before results are available, as opposed to what we can offer with the Idylla™ technology."*

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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, 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_.

1 A companion diagnostic (CDx) test is a test used as a companion to a therapeutic drug that helps predict if a patient is likely to respond to a treatment or not
2 FFPE = formalin fixed, paraffin embedded
3 Processed into FFPE cell blocks
4 First collaboration expansion was announced in May 2021 and was supported by AstraZeneca's large prospective lung cancer FACILITATE study (Hummel M. et al, "FACILITATE: a real-world multicenter prospective study investigating the utility of a rapid, fully automated RT-PCR assay vs reference methods (RM) for detecting epidermal growth factor receptor mutations (EGFRm) in NSCLC", ESMO Virtual Congress 2020 (19-21 Sept 2020), first published online on 14 Sept 2020. Poster was presented at ESMO 2020 (European Society for Medical Oncology), poster reference 1205P
5 Source: https://www.astrazeneca.com/our-focus-areas/oncology/at-the-forefront-of-lung-cancer-treatment.html, last consulted on 10 June 2022

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