PRESS RELEASE



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Biocartis and Amgen sign a RAS Biomarker Testing Collaboration in Europe

Mechelen, Belgium, 22 December 2016 - Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced the signing of a new collaboration agreement with Amgen, a leading biotechnology company. The new agreement, which builds on the existing collaboration between both companies announced on 3 February 2016¹, aims at accelerating access to RAS biomarker information in up to 10 European countries.

For metastatic colorectal cancer (mCRC) patients, timely information on the presence of mutations in the RAS genes (KRAS, NRAS) and BRAF² is critical for treatment selection. Current technologies to assess RAS gene mutational status used by hospitals are complex to perform and on average, require up to one month to provide results. In certain countries, RAS testing samples have to be sent abroad, which further delays results and treatment selection for patients.

Based on the experience from the existing collaboration, Biocartis and Amgen will now aim to enable several dozen additional selected hospitals in Europe to accelerate access to RAS biomarker information, from up to one month to same-day results for mCRC patients, using Biocartis' Idylla[™] platform and RAS tests.

Biocartis' CE-marked RAS mutations test offering has a turn-around-time of only two hours with less than two minutes hands-on time. Furthermore, the Idylla[™] platform can be operated in any hospital laboratory, independent of hospital size, available infrastructure and experience level.

Ulrik Cordes, EVP Pharma Collaborations and Companion Diagnostics, commented: "We are very pleased to have expanded our agreement with Amgen. This strong partnership will help to further boost the footprint of Idylla[™] systems in Europe. Additionally, it is another step towards our ultimate goal of improving patient access to rapid and reliable biomarker information with the potential to enable more rapid treatment selection."

The expansion of Biocartis' agreement with Amgen is part of Biocartis' active partnership strategy for its Idylla[™] platform, aimed at enabling personalized medicine for patients across the globe through rapid, highly accurate and easy to use high precision diagnostic solutions. The collaboration also includes the possibility to use the Idylla[™] platform in scientific studies to further understand the role of biomarkers in clinical practice.

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More information:

Renate Degrave Manager Corporate Communications & Investor Relations e-mail <u>rdegrave@biocartis.com</u> tel +32 15 631 729 mobile +32 471 53 60 64 <u>@Biocartis</u> <u>www.linkedin.com/Biocartis</u>

¹ The collaboration announced on 3 February 2016 focused on selected reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey.
² Following the latest clinical practice recommendations of the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO).
ASCO: Allegra et al, Extended RAS Gene Mutation Testing in Metastatic Colorectal Carcinoma to Predict Response to Anti–Epidermal Growth Factor Receptor Monoclonal Antibody Therapy: American Society of Clinical Oncology Provisional Clinical Option Update 2015, J Clin Oncol 2016, 34:179-185, http://accopubs.org/doi/pdf/10.1200/jco.2015.63.9674. See also http://aicasym.org/aesco-updates-guideline-include-testing-new-ras-mutations. ESMO: Van Cutsem et al, ESMO consensus quidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 2016. 8:1386-1422.

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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 launched the Idylla[™] platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers six oncology tests and two infectious disease tests. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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