



PRESS RELEASE

Biocartis and Amgen Collaborate to Offer Rapid RAS Biomarker Testing to Selected Hospitals and Clinics in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey

- **Biocartis and Amgen have entered into a collaboration to evaluate Idylla™ RAS testing as tool for rapid decentralized testing in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain, and Turkey**
- **Assessment of RAS (KRAS/NRAS) biomarker status is important in treatment selection for patients with metastatic colorectal cancer**
- **With the Idylla™ system, RAS testing can be accelerated from several weeks to same-day results**
- **The collaboration underlines Amgen's and Biocartis' commitment to patients in oncology in offering high precision medicine and high precision diagnostics**

Mechelen, Belgium, February 3, 2016 – Biocartis today announced that it has entered into collaboration with Amgen, a leading biotechnology company, to offer its new RAS biomarker tests to hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey. The aim of the collaboration is to accelerate access to RAS biomarker information in the selected countries.

For patients with metastatic colorectal cancer (mCRC), timely information on the presence of mutations in the RAS genes (KRAS and NRAS) is critical in treatment selection. Technologies to assess RAS gene mutational status, currently used by hospitals across the globe, are complex to perform and on average, require several weeks to provide results. In certain countries, local RAS testing is unavailable and samples have to be sent abroad for testing, which further delays availability of results and consequently, treatment selection for patients. With the Biocartis Idylla™ system, RAS biomarker testing can be performed locally and in a significantly shorter timeframe.

The Idylla™ KRAS Mutation Test and Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay together provide for a complete mCRC mutation analysis¹ from two slices of so-called formalin-fixed paraffin embedded (FFPE) tumor tissue. With a turn-around-time of around two hours and each test requiring less than two minutes of hands-on time, the Idylla™ system can be operated in any hospital laboratory, independent of hospital size, available infrastructure and experience level. For the first time in the molecular pathology field, the Idylla™ test allows performance of a complete RAS analysis on a same-day basis, opening up the route towards faster treatment selection.

Under the current collaboration, Amgen will make Idylla™ RAS testing available to several reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey.

Ulrik Cordes, Chief Commercial Officer Biocartis, commented: *"We are very pleased to work with Amgen to accelerate the roll-out of our state-of-the-art Idylla™ extended RAS testing solutions in hospitals worldwide. We view the fact that leading biopharmaceutical companies are electing to utilize our recently launched Idylla™ solutions, to improve access to advanced high precision diagnostic testing, as a confirmation of the quality of our products. Our collaboration will significantly enable improved patient care in countries where cancer patients, until now, have had to wait weeks, and sometimes months, to get critical diagnostic information. Together with Amgen, we can now secure much faster access to the right treatment for certain patients, thereby reducing anxiety for the affected patients and their relatives."*

Amgen has played a significant role in the advancement of personalized medicine, applying cutting-edge science and technology in its efforts to target therapies to the patients who are most likely to benefit.

Using molecular approaches to identify unique, genetic signatures in mCRC has the potential to help improve treatment outcomes. Of the few biomarkers in colorectal cancer, RAS genes (KRAS, NRAS) have a validated impact on treatment outcomes.

Biocartis' mission is to become a leading player in the molecular diagnostics space by providing innovative high precision diagnostic solutions that allow instant, global access to accurate, 'first time right' molecular information from any biological sample. Thereto, the company is continuing to develop a range of molecular tests for oncology and infectious diseases to enable fast and effective diagnosis, treatment selection and treatment progress monitoring. The current collaboration with Amgen underlines Biocartis' commitment to make its solutions available to patients across the globe.

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For more information:

Biocartis

Renate Degrave (Corporate Communications & Investor Relations)
+32 15 632 600 | press@biocartis.com

About colorectal cancer

Colorectal cancer is the third most common cancer worldwide, with approximately 1.2 million cases occurring globally each year.^{2,3} Approximately 20 percent of colon cancers are diagnosed at the metastatic stage, when the disease has already spread to distant organs, a diagnosis associated with only a 12 percent five-year survival rate. Using molecular approaches to identify unique genetic signatures in mCRC has the potential to help improve treatment outcomes. Of the few biomarkers in colorectal cancer, RAS genes (KRAS, NRAS) have a validated impact on treatment outcomes.^{2,3}

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. Idylla™ addresses the growing demand for personalized medicine by aiming to allow fast and effective treatment selection and treatment progress monitoring.

Biocartis launched the Idylla™ platform commercially in September 2014 together with its first assay to identify BRAF mutations in metastatic melanoma. In June 2015, the Idylla™ KRAS Mutation Test for colorectal cancer was launched, followed by the first infectious disease assay in November 2015, the Idylla™ Respiratory (IFV-RSV) Panel, developed in collaboration with Janssen Diagnostics. In December 2015, Biocartis launched its Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay as a Research Use Only (RUO). 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. Further information can be found at www.biocartis.com.

References

¹ Combined, the two Idylla™ RAS tests allow for detection of 39 different clinically actionable KRAS and NRAS mutations at high sensitivity in line with the novel clinical guidelines as recently issued by the European Society for Medical Oncology, American Society of Clinical Oncology, the Association for Molecular Pathology and the National Cancer Institute.

² Fight Colorectal Cancer. Biomarker Testing for Colorectal Cancer: Common Biomarker Tests for Colon Cancer. Accessed on Feb 1, 2016: available at: <http://fightcolorectalcancer.org/fightcrc-fightit/biomarker-testing-for-colorectal-cancer/>.

³ Colon Cancer Alliance. Get Information: Treatment: Biomarkers. Know Your Biomarker. Accessed on Feb.1, 2016: available at: <http://www.ccalliance.org/get-information/treatment/biomarkers/>.