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Biocartis and Amgen Sign Companion Diagnostic Agreement for Idylla™ RAS Biomarker Tests

Agreement aims to deliver faster biomarker results to realize more informed treatment decisions

Mechelen, Belgium, 4 December 2017 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced the signing of a companion diagnostic[1] (CDx) development agreement with Amgen, a leading biotechnology company (NASDAQ: AMGN), for the Idylla™ RAS biomarker tests. The aim of the agreement is to register the Idylla™ RAS biomarker tests with the US Food and Drug Administration (FDA) as a companion diagnostic test for Amgen's drug Vectibix® (panitumumab). Vectibix® is the first and only fully human monoclonal anti-epidermal growth factor receptor (EGFR) antibody indicated for certain metastatic colorectal cancer (mCRC) patients with wild-type RAS[2].

RAS testing is an essential predictive biomarker to determine the treatment plan for patients with mCRC. Today, RAS testing in the US is not performed systematically for all patients, and if done, results can be delayed, which can affect patients' outcomes.

The CDx agreement further builds on Biocartis' and Amgen's collaborations[3] in Europe that are focused on accelerating results of RAS biomarker testing from up to one month to, in principle, same-day results for mCRC patients, using Biocartis' Idylla™ platform and Idylla™ RAS biomarker tests. US FDA approval of the Idylla™ RAS biomarker tests could allow for a more widespread RAS clinical testing, regardless of the clinical practice size, available lab infrastructure or experience level, and could enable same-day turnaround times.

Under the agreement, Biocartis will pursue a premarket approval (PMA[4]) for the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the US FDA. Amgen will provide financial and operational support to Biocartis for the PMA process.

The two Idylla™ RAS biomarker tests together allow for a simultaneous detection of 44 clinically relevant mutations for colorectal cancer, operating directly from formalin-fixed paraffin embedded (FFPE) tumor slices.

Ulrik Cordes, EVP Companion Diagnostics of Biocartis, **commented**: "*We are very pleased to further strengthen our collaboration with Amgen. This new agreement is a testimony to what the Idylla™ technology can bring to patients in helping to overcome the current challenges of RAS testing in the US market. Pursuing US FDA approval of our CDx Idylla™ RAS tests, in collaboration with Amgen, will enable laboratories throughout the US to reduce waiting times and provide timely access to biomarker status for the optimal selection of therapies for colorectal cancer patients. This is very much in line with the core of our mission to make personalized medicine an everyday reality.*"

"*Amgen has been a pioneer in personalized medicine for colorectal cancer, and we are committed to advancing patient care with the identification of appropriate biomarkers to aid optimal treatment selection,*" said **Greg Friberg, vice president of Global Development, Oncology at Amgen**. "*We know that mutation status provides actionable information when deciding on a first-line treatment option in mCRC patients. We are excited to*

[1] A 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] Defined as wild-type in both *KRAS* and *NRAS* genes.
[3] Biocartis and Amgen announced a first collaboration on 3 February 2016, aimed at accelerating access to RAS biomarker information for metastatic colorectal cancer (mCRC) patients in a number of selected countries worldwide (Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey) and expanded their collaboration on 22 December 2016 to additional selected hospitals in Europe.
[4] Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. PMA is the most stringent type of device marketing application required by FDA. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Source: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/, last consulted on 29 November 2017.

collaborate with Biocartis to apply novel technologies as we seek to deliver expedited RAS biomarker test results that will help to identify patients that may benefit the most from Vectibix."

The announcement today marks an important next step in the expansion of Biocartis' CDx business, which is aimed at a market expected to grow 20% annually worldwide[1], reaching USD 6.5 billion by 2022[5].

Financial details on the CDx agreement with Amgen are not disclosed.

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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 twelve oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Forward-looking statements

This press release may contain forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements speak only as of the date of this press release. Biocartis expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release. You should not place undue reliance on forward-looking statements.

[5] MarketsandMarkets, 2016, "Companion Diagnostics Market by Technology (PCR, IHC, NGS, ISH), Indication (Breast cancer, NSCLC, Colorectal cancer, Neurological disorders, Infectious Diseases), End User (Pharmaceutical & Biopharmaceutical Companies, Reference Lab) - Global Forecast to 2022."