



PRESS RELEASE

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## Important milestone in Biocartis-Merck collaboration with launch of second liquid biopsy assay

**Mechelen, Belgium, 2 March 2017** - Biocartis Group NV ('Biocartis' or 'the Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (Research Use Only or RUO). Being the third<sup>1</sup> liquid biopsy test for Biocartis, the newly launched assay also marks an important milestone in the partnership with the leading science and technology company Merck<sup>2</sup>. This collaboration is aimed at jointly developing and commercializing new liquid biopsy RAS biomarker tests for metastatic colorectal cancer (mCRC). The first assay under the collaboration, the Idylla™ ctKRAS Mutation Assay (RUO), was launched in December 2016.

Access to rapid and easy-to-use molecular diagnostic tests is essential to understand individual cancer-driving gene mutations in mCRC, opening doors to timely cancer treatment decision-making. Liquid biopsy tests<sup>6</sup> have demonstrated clear benefits as these tests are minimally invasive, fast and easy to perform compared to more traditional tumor tissue-based testing.

The new Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO), operating on Biocartis' molecular diagnostics Idylla™ platform, is a fully automated sample-to-result assay that operates directly on 1 ml of blood plasma. Intended for the qualitative and sensitive detection of 25 mutations (18 NRAS mutations, 5 BRAF mutations and 2 EGFR S492R mutations), the assay requires less than 1 minute of hands-on time and has a turnaround time of less than 2 hours. The assay further extends Biocartis' colorectal cancer test offering, now consisting of two CE-marked solid biopsy tests (together detecting 44 mutations directly from a slice of FFPE<sup>3</sup> tumor tissue each) and two liquid biopsy assays<sup>4</sup> (available for research use only, together detecting 46 mutations directly from 1 ml of blood plasma each).

**Erwin Sablon, Head of R&D and Alliance Management Biocartis, commented:** *"We are very pleased to have reached this important milestone, the development of two liquid biopsy RAS biomarker assays, thanks to the successful partnership with Merck. We now have one of the broadest mCRC test offerings, enabling easy and rapid access to molecular diagnostic testing. Because blood plasma is easy to obtain, we anticipate that our liquid biopsy tests in the future will further improve patient access to high precision biomarker testing, which is a cornerstone in high precision medicine."*

Under the partnership with Merck, announced in January 2016, CE-marked IVD versions of the liquid biopsy RAS biomarker assays are expected to be launched in the second half of 2017. Once these have been validated for diagnostic use, the tests will be made available to medical centers across the world<sup>5</sup>.

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<sup>1</sup> The Idylla™ ctBRAF Mutation Assay, the Idylla™ ctKRAS Mutation Assay and the newly launched Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay are Research Use Only (RUO), not for use in diagnostic procedures.

<sup>2</sup> Merck KGaA, Darmstadt, Germany.

<sup>3</sup> Formalin-fixed paraffin embedded.

<sup>4</sup> The Idylla™ KRAS Mutation Assay and the Idylla™ NRAS-BRAF Mutation Assay are CE-marked IVD tests which can be used in diagnostic procedures. The Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay are Research Use Only (RUO) and not for use in diagnostic procedures.

<sup>5</sup> The collaboration does not include the US, China and Japan.

### **About liquid biopsy testing**

Research over the last few years has shown that fragments of tumor DNA are shed into the blood from primary tumors or metastatic sites<sup>6</sup>. These circulating DNA fragments can be used for diagnostic purposes, such as providing molecular information for treatment selection, or for monitoring disease progression in patients undergoing treatment. According to J.P. Morgan, the global market of liquid biopsy tests is estimated to reach \$20 billion by 2020.

### **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 eight oncology tests and two infectious disease tests. More information: [www.biocartis.com](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

### **About Merck**

Merck is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2014, Merck generated sales of € 11.3 billion in 66 countries. Founded in 1668, Merck is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' 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. As a result, the Company expressly disclaims any obligation or undertaking to release any update 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. 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.*

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<sup>6</sup> Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.