

News Release

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Merck KGaA, Darmstadt, Germany and Biocartis to Collaborate on New Liquid Biopsy Technology for RAS Biomarker Testing

- **Merck KGaA, Darmstadt, Germany becomes first pharmaceutical company to collaborate with multiple diagnostic providers to support RAS biomarker testing**
- **Collaboration allows Merck KGaA, Darmstadt, Germany to provide complementary molecular testing solutions to various laboratory segments**
- **Biocartis' fully automated Idylla™ system will enable more clinics to assess RAS mutation status in metastatic colorectal cancer (mCRC) patients**
- **New diagnostic test will be fast, minimally invasive, easy-to-perform and support timely decision making**

Darmstadt, Germany, January 7, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that it has signed a collaboration agreement with Biocartis for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC). The test will be developed on Biocartis' innovative, fully automated molecular diagnostics system, Idylla™, which is designed to offer accurate and reliable molecular information from virtually any biological sample in virtually any setting. The new test aims to support clinical practice in performing integrated liquid biopsy RAS biomarker tests, independently of the laboratories' volume of testing or level of expertise.

Understanding metastatic colorectal cancer (mCRC) patients' individual biomarker status is key to support timely treatment decision-making.

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Merck KGaA

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“Through this collaboration, our desire is to have more metastatic colorectal cancer patients gain access to liquid biopsy RAS testing, regardless of their geographical location,” said Rehan Verjee, Chief Marketing and Strategy Officer of Merck KGaA, Darmstadt, Germany’s biopharma business. “As the first pharmaceutical company to collaborate with multiple diagnostic providers of liquid biopsy RAS testing, we are living our commitment to supporting patients and physicians by going beyond treatment. The Biocartis technology will be complementary to other technology previously developed, and will allow for liquid biopsy RAS offerings to a wide range of lab segments, regardless of size and expertise levels.”

The Idylla™ system is a fully automated sample-to-result PCR-based (polymerase chain reaction) molecular diagnostics system. It is designed to offer real-time, reliable and sensitive molecular diagnostic tests. Whereas most of today’s solutions only look for the most prevalent RAS mutations, the Idylla™ RAS test, comprising two Idylla™ cartridges, will be designed to detect an extended panel of RAS mutations. In addition, the new test will also provide a BRAF V600 mutation analysis directly integrated with the Idylla™ RAS test, to allow clinicians to evaluate BRAF and RAS mutation status simultaneously. Based on a direct sample of only 2 ml of blood plasma, the test aims to provide high sensitivity and ease-of-use. The test will be designed to require less than 2 minutes of hands-on time and a turnaround time of approximately 2 hours, enabling clinical decision-making in a timely manner.

“Today, complex diagnostic laboratory infrastructure and specialized expertise requirements are important barriers when it comes to the implementation of personalized medicine on a global scale.” said Rudi Pauwels, CEO Biocartis. “We are pleased to partner with Merck KGaA, Darmstadt, Germany, who supports us in putting personalized medicine into daily practice with this collaboration, through the development of rapid and accurate tests on the Idylla™ system. After having already launched solid biopsy RAS tests, the Idylla™ liquid biopsy RAS test is a logical next step in our rapidly expanding menu of oncology tests.”

Merck KGaA, Darmstadt, Germany and Biocartis plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centers across the world, excluding the U.S., China and Japan. The test will be available for Research Use Only (RUO) in H2

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2016 and is shortly thereafter planned to be submitted for a CE Mark. A concordance study is currently also being undertaken to substantiate the value of the test.

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About mCRC

Approximately half of patients with mCRC have RAS wild-type tumors and half have RAS mutant tumors.¹ Results from studies assessing RAS mutation status in patients with mCRC have shown that anti-epidermal growth factor receptor (EGFR) monoclonal antibody therapies, such as Erbitux® (cetuximab), can improve outcomes in patients with RAS wild-type mCRC.²⁻⁶ Colorectal cancer (CRC) is the third most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually.⁷ An estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.⁷ Almost 55% of CRC cases are diagnosed in developed regions of the world, and incidence and mortality rates are substantially higher in men than in women.⁷

References

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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. 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. Its second assay, a KRAS Mutation panel for colorectal cancer, was launched in June 2015. 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.

About Idylla™

Idylla™, Biocartis' fully automated, real-time PCR based molecular diagnostics system, is designed to offer fast and easy access to clinical molecular diagnostic information, anywhere and anytime. The Idylla™ platform covers the entire process from sample to result in a time frame of 35 to 150 minutes with less than two minutes hands-on time. Idylla™ is applicable for a wide range of clinical sample types and can analyze both RNA and DNA. The fully integrated system enables clinical laboratories to perform a broad range of applications in oncology, infectious diseases and beyond.

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The Idylla™ system's first diagnostic tests, the Idylla™ BRAF Mutation Test for metastatic melanoma, the Idylla™ KRAS Mutation Test for colorectal cancer and the first infectious disease test, the Idylla™ Respiratory (IFV-RSV) Panel developed in collaboration with Janssen Diagnostics, have obtained CE-IVD marking. Further information can be found at: www.idylla.com.

About Erbitux

Erbitux® is a highly active IgG1 monoclonal antibody targeting the epidermal growth factor receptor (EGFR). As a monoclonal antibody, the mode of action of Erbitux is distinct from standard non-selective chemotherapy treatments in that it specifically targets and binds to the EGFR. This binding inhibits the activation of the receptor and the subsequent signal-transduction pathway, which results in reducing both the invasion of normal tissues by tumor cells and the spread of tumors to new sites. It is also believed to inhibit the ability of tumor cells to repair the damage caused by chemotherapy and radiotherapy and to inhibit the formation of new blood vessels inside tumors, which appears to lead to an overall suppression of tumor growth.

The most commonly reported side effect with Erbitux is an acne-like skin rash that seems to be correlated with a good response to therapy. In approximately 5% of patients, hypersensitivity reactions may occur during treatment with Erbitux; about half of these reactions are severe.

Erbitux has already obtained market authorization in over 90 countries world-wide for the treatment of colorectal cancer and for the treatment of squamous cell carcinoma of the head and neck (SCCHN).

Merck KGaA, Darmstadt, Germany licensed the right to market Erbitux outside the US and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998. Merck KGaA, Darmstadt, Germany has an ongoing commitment to the advancement of oncology treatment and is currently investigating novel therapies in highly targeted areas.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 40,000 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 KGaA, Darmstadt, Germany, generated sales of € 11.3 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.