PRESS RELEASE

Biocartis launches world's first fully automated liquid biopsy assay and its second tissue assay for colorectal cancer

Launch of two new tests on its Idylla™ molecular diagnostics platform strengthens the company's assay menu

Mechelen, Belgium, 22 December 2015 - Biocartis (Euronext Brussels: **BCART**), an innovative molecular diagnostics company, today announces the launch of two new products on its molecular diagnostics platform Idylla™. The Idylla™ ctBRAF Mutation Assay uses blood plasma as a sample, which is far less invasive to obtain compared to tissue biopsies. As plasma samples can repeatedly be obtained and do not require prior information on the tumour location, liquid biopsy testing opens up a range of new possibilities in terms of efficient cancer monitoring and treatment. The second assay launched by Biocartis is the tissue biopsy Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay. This assay now allows Biocartis to offer a complete RAS-BRAF analysis that can be performed on a same-day basis, which opens up the route towards faster treatment selection ('same day results'). Both assays are initially launched as Research Use Only (RUO) products.

Rudi Pauwels, CEO Biocartis, adds: "*We are thrilled about the two new assays, which strengthen our growing Idylla™ menu. Liquid biopsy testing has the potential to significantly improve the early diagnosis and monitoring of cancer and Biocartis can now enable both tissue and liquid biopsy testing on the same instrument, in the same lab. With our new Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, we are now enabling same-day RAS testing. These developments, in line with our stated menu strategy at the time of the third quarter results, underline our success in delivering high precision diagnostics for high precision medicine in virtually any setting, to patients worldwide*."

Launch of first liquid biopsy assay

Research over the last few years has shown that fragments of tumour DNA are shed into the blood from primary tumours or metastatic sites[1]. 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. This observation has led to the development of technologies for liquid biopsy testing. According to J.P. Morgan, the global market of liquid biopsy tests is estimated to reach $20 billion by 2020.

The Idylla™ ctBRAF Mutation Assay is the world's first and only fully automated liquid biopsy assay that can potentially act as a substitute for tissue biopsy testing in melanoma, colorectal and lung cancers, as well as conditions such as hairy cell leukaemia and histiocytosis[2]. The assay has a turnaround time of approximately 90 minutes with less than one minute of hands-on time.

With an earlier prototype of the assay, Schreuer et al.[3] have shown that analysis of BRAF mutant circulating tumour DNA (ctDNA) from plasma using Idylla™ allows for a rapid determination of the BRAF status in samples from patients with advanced melanoma, and that the amount of mutant BRAF ctDNA may be an indication of tumour growth. The ability to rapidly analyse BRAF mutations in plasma of patients holds promise as a therapeutic monitoring tool for patients with advanced BRAF V600 mutant melanoma.

[1] Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.
[2] Histiocytosis is a general name for a group of disorders or "syndromes" that involve an abnormal increase in the number of immune cells that are called histiocytes. Source: https://www.nlm.nih.gov/medlineplus/ency/article/000068.htm, December 2015.
[3] Schreuer et al. Quantitative assessment of BRAF V600 mutant cell-free tumor DNA from plasma as a diagnostic and therapeutic biomarker in pts with BRAF V600 mutant melanoma. J Clin Oncol 33, 2015 (suppl; abstr 9015).

Prof. Dr. Bart Neyns, Head of Medical Oncology at the University Hospital Brussels, said: "*Liquid biopsies represent a number of benefits. Theoretically, liquid biopsies allow, based on a simple blood sample, for patients rapidly deteriorating from cancer, to receive a diagnosis and optimal treatment on the very same day.*"

In October of this year, Biocartis announced that it has received a grant from the Flemish Agency for Innovation by Science and Technology (IWT) to support the research and development of liquid biopsy tests.

Same-day RAS testing

The tissue biopsy Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay is complemented by the current already CE-marked Idylla™ KRAS Mutation Test (tissue biopsy test). Together, these provide for a complete metastatic colorectal cancer (mCRC) mutation analysis, from two slices of so-called formalin-fixed paraffin embedded (FFPE) tumour tissue.

CRC is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually[4]. According to the International Agency for Research on Cancer, 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.

At the 40th European Cancer Congress in September 2015 (Vienna, Austria), Biocartis presented a study called 'A solution for same-day extended RAS testing'. For the first time in the molecular pathology field, this assay allows to perform a complete RAS analysis on a same-day basis, opening up the route towards faster treatment selection.

The Idylla™ KRAS Mutation Test and new Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay together are able to detect 39 KRAS and NRAS mutations ("extended RAS") at high sensitivity, in line with the novel clinical guidelines as recently issued by ASCO/AMP/NCI[5] (including 5% limit of detection). The new assay detects 18 NRAS mutations as well as five BRAF mutations, for which testing is now mandatory in patients with mCRC[1]. The assay also uniquely detects the so-called EGFR S492R mutation, which is associated with resistance to certain anti-EGFR therapies.

Geert Maertens, Chief Scientific Officer Biocartis, **commented**: "*With our new Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, we can now offer a complete RAS-BRAF analysis for all clinically actionable biomarkers, in line with the newest clinical guidelines in mCRC, to be performed on a same-day basis. In addition, the assay includes the recently discovered EGFR S492R mutation[6], illustrating Biocartis' continuous drive for innovation.*"

Both products are specifically developed on Biocartis' fully integrated Idylla™ molecular diagnostics platform, which was commercially launched in September 2014. Since then, four oncology and one infectious disease test have been launched for use on the Idylla™ platform.

Over the coming years, Biocartis plans to develop a range of liquid biopsy tests, alongside the ongoing development of tissue biopsy tests. The next liquid biopsy oncology tests in development are the Idylla™ extended RAS tests for colorectal cancer (i.e. KRAS and NRAS).

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[4] Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available at: http://globocan.iarc.fr. Last accessed December 2015.
[5] ASCO = American Society of Clinical Oncology, AMP = Association for Molecular Pathology and NCI = National Cancer Institute.
[6] The mutation was discovered in 2012 by Prof. Montagut and Dr. Albanell's team at the Medical Oncology Service, Hospital del Mar (Barcelona, Spain), where it was shown that the mutation blocks binding of the anti-EGFR antibody cetuximab, making that treatment ineffective.

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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 allowing fast and effective treatment selection and treatment progress monitoring.

Biocartis launched the Idylla™ platform commercially in September 2014 together with its first test 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 test in November 2015, the Idylla™ Respiratory (IFV-RSV) Panel, developed in collaboration with Janssen Diagnostics. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas respectively represent the fastest growing and largest segments of the MDx market worldwide. More information: www.biocartis.com