PRESS RELEASE

Study demonstrating Biocartis' BRAF liquid biopsy assay is as good as more invasive tissue tests published in renowned journal of American Association for Cancer Research

Test can predict therapy response over the course of the cancer treatment

Mechelen, Belgium, 23 May 2016 – Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the recent publication of a research study[1] demonstrating that testing for BRAF V600 mutations in blood plasma is as good as more invasive tissue tests[2]. The study by Dr. Filip Janku, PhD, assistant professor of Investigational Cancer Therapeutics at MD Anderson Cancer Center (Houston, US), was published in Molecular Cancer Therapeutics, a journal of the American Association for Cancer Research (AACR), the world's largest professional association related to cancer research. The press release of AACR announcing the publication of this study can be found here.

In this study, Dr. Janku and his team demonstrated that testing for BRAF V600 mutations in circulating tumour (ct)DNA from plasma, using Biocartis' Idylla™ ctBRAF Mutation Assay[3], was concordant with standard tests using tumour tissue samples and could generate results in an unprecedented short turnaround time of 90 minutes. The study confirms that the Idylla™ ctBRAF Mutation Assay can act as a faster and minimally invasive substitute for invasive tissue biopsy testing in advanced cancers such as melanoma or colorectal cancers, which underlines that the test is perfectly suited for treatment monitoring.

Research over the last few years has shown that fragments of tumour DNA are shed into the blood from primary tumours or metastatic sites[4]. 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.

In the current study, plasma samples collected from 160 patients with a range of advanced cancers with known BRAF V600 mutation status were tested with the Idylla™ ctBRAF Mutation Assay[3]. Dr Janku and his team found that the test had 88 percent concordance with the results from the tissue tests that used solid, paraffin-embedded tissues, in samples collected at baseline. The concordance increased to 90 percent when results from samples collected at any time point during the course of the treatment were compared. The researchers also found that the amount of BRAF V600 mutant circulating tumour (ct)DNA, as detected by the Idylla™ platform[3], was predictive of overall survival of the patients: in patients with a BRAF-mutant circulating tumor (ct)DNA percentage of 2 or less, overall survival was 10.7 months, compared with 4.4 months in those who had more than 2 percent of BRAF V600 mutations in their samples.

Geert Maertens, Chief Scientific Officer of Biocartis, stated: "*We are very excited about this AACR publication. It's a great recognition of the outstanding performance of Biocartis' first fully automated liquid biopsy assay, the Idylla™ ctBRAF Mutation Assay[3]. The study demonstrates that this test can act as a faster and minimally invasive test, complementary to tissue biopsy testing in advanced cancers such as melanoma or colorectal cancers. Another important outcome was the connection between the level of BRAF V600 mutations measured with the test, and the time to treatment failure (TTF), which underlines the test is perfectly suited for treatment monitoring.*"

Dr. Filip Janku, MD, PhD at MD Anderson Cancer Center, Houston, US, added: "*We demonstrated that testing for BRAF V600 mutations in plasma circulating tumor (ct)DNA using the Idylla™ ctBRAF Mutation Assay[3] is feasible, has comparable sensitivity and specificity to other Polymerase Chain Reaction (PCR) or next-generation sequencing methods, and has an unprecedented short turnaround time. This study now confirms that the Idylla™ ctBRAF Mutation Assay[3] can act as a faster and less invasive substitute for tissue biopsy testing in*

[1] Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. Mol Cancer Ther (2016) 15(6): 1–8.
[2] Involving the need for taking tumour tissue biopsy.
[3] Idylla™ ctBRAF Mutation Assay is for Research Use Only and not for use in diagnostic procedures. The Idylla™ platform and the Idylla™ ctBRAF Mutation Assay are not for sale in the USA and Canada.
[4] Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.

advanced cancers such as melanoma or colorectal cancers, and the test has unique features to monitor treatment efficiency and predict survival of patients."

The performance of the Idylla™ ctBRAF Mutation Assay[3] of Biocartis was also confirmed in another recent study[5] by Prof. Bart Neyns (Head of Medical Oncology, University Hospital Brussels) and his team. Published in the Journal of Translational Medicine, this study also concludes that the quantitative analysis of BRAF V600 mutant circulating tumour (ct)DNA in plasma has unique potential as a tool for therapeutic monitoring in metastatic melanoma patients treated with BRAF/MEK inhibitors.

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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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 has four oncology tests and one test for infectious disease on the market. More information: www.biocartis.com. Follow us at @Biocartis .

About the American Association for Cancer Research

Founded in 1907, the American Association for Cancer Research (AACR) is the world's oldest and largest professional organization dedicated to advancing cancer research and its mission to prevent and cure cancer. AACR membership includes more than 35,000 laboratory, translational, and clinical researchers; population scientists; other health care professionals; and patient advocates residing in 101 countries. The AACR marshals the full spectrum of expertise of the cancer community to accelerate progress in the prevention, biology, diagnosis, and treatment of cancer by annually convening more than 30 conferences and educational workshops, the largest of which is the AACR Annual Meeting with nearly 19,300 attendees. In addition, the AACR publishes eight prestigious, peer-reviewed scientific journals and a magazine for cancer survivors, patients, and their caregivers. The AACR funds meritorious research directly as well as in cooperation with numerous cancer organizations. As the Scientific Partner of Stand Up To Cancer, the AACR provides expert peer review, grants administration, and scientific oversight of team science and individual investigator grants in cancer research that have the potential for near-term patient benefit. The AACR actively communicates with legislators and other policymakers about the value of cancer research and related biomedical science in saving lives from cancer. For more information about the AACR, visit www.AACR.org.

[5] Schreuer et al. Quantitative assessment of BRAF V600 mutant circulating cell-free tumor DNA as a tool for therapeutic monitoring in metastatic melanoma patients treated with BRAF/MEK inhibitors. J Transl Med (2016) 14:95.