PRESS RELEASE

Biocartis' KRAS Mutation Test receives CE-IVD marking

Biocartis' Idylla™ KRAS Mutation Test is the first fully automated IVD KRAS Test to match novel guidelines – capable of detecting an extended panel of 21 KRAS mutations with high sensitivity.

Mechelen, Belgium, **June 24th 2015:** Biocartis (Euronext Brussels: **BCART**), an innovative molecular diagnostics company, today announced the launch of its CE-IVD Idylla™ KRAS Mutation Test, a sample-to-result test for the fast, accurate and reproducible detection of 21 relevant mutations in the KRAS oncogene.

The Idylla™ KRAS Mutation Test is the first fully-automated CE-IVD test available for routine use that detects all clinically relevant driver mutations of the KRAS oncogene in tissue of colorectal cancers (CRC) at a sensitivity of 5% as recommended according to ESMO[1], NCCN[2], and the recently issued CAP/AMP/ASCO guidelines[3]. Unique to the Idylla™ KRAS Mutation Test is its ability to detect all relevant mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) of the KRAS gene.

Validation studies and pre-market trials on more than 500 mCRC patient samples have demonstrated the excellent accuracy of the Idylla™ KRAS Mutation Test. During the validation study, the Idylla™ KRAS Mutation Test detected 8% more mutations than the reference test. Between-lab reproducibility studies showed a 100% agreement between all participating sites, demonstrating that the Idylla™ KRAS Mutation Test is easy to implement and highly standardized.

The Idylla™ KRAS Mutation Test runs on the Idylla™ platform and provides accurate and actionable results in an unprecedented timeframe of approximately two hours. Hands-on time is less than two minutes as the formalin-fixed, paraffin embedded (FFPE) tissue is directly inserted into the Idylla™ cartridge without any prior deparaffinization or other pre-processing steps.

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[1] E. Van Cutsem, B. Nordlinger & A. Cervantes. On behalf of the ESMO Guidelines Working Group. Advanced colorectal cancer: ESMO clinical practice guidelines for treatment. Annals of Oncology 21 (Supplement 5): v93–v97, 2010

[2] NCCN Clinical Practice Guidelines Colon Cancer, vs. 2, 2015

[3] http://www.amp.org/committees/clinical_practice/documents/20150327CRCMMDraftRecommendationsforOCP-UPDATEDfinaldraft_001.pdf

Dr. Alberto Bardelli, Director of the Laboratory of Molecular Genetics, Institute for Cancer Research and Treatment, Torino, Italy, commented: *"Biocartis has crafted an innovative KRAS test that offers exactly what is currently needed in the field: the Idylla KRAS Mutation Test has an excellent sensitivity and detects 21 mutations in all of the relevant codons of KRAS exons 2, 3 and 4. These unique features, combined with ease of use and short turnaround time, are expected to be of benefit to any lab."*

The Idylla™ KRAS Mutation Test is the second test launched by Biocartis and a cornerstone in a set of highly standardized and sensitive tests around metastatic colorectal cancer. A similar extended NRAS panel, which can be combined with KRAS for the detection on an extended panel of 40 RAS mutations in combination with BRAF and EGFR492 mutations, is currently in development.

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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 assay to identify BRAF mutations in metastatic melanoma. Its second assay, a KRAS mutation panel for colorectal cancer has been 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™ (www.idylla.com)

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. Idylla™ and the system's first assays, the Idylla™ BRAF Mutation Test for metastatic melanoma and Idylla™ KRAS Mutation Test have obtained CE-IVD marking.

About KRAS Mutation

KRAS is a protein which plays a role in cell proliferation, angiogenesis, migration, cell survival and cell adhesion. When KRAS is mutated, it leads to uncontrolled cell growth and division that may result in cancer. Biocartis estimates that around 45% of patients in Europe with colorectal cancer, roughly 100,000 people, are eligible for KRAS testing.[4]

4 Globocan 2012 - Estimated incidence (all except US)