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Studies on Idylla™ MSI and RAS liquid biopsy tests to be presented at ESMO congress

Mechelen, Belgium, 19 October 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that two studies, one treatment outcome study[1] making use of the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD) and one[2] on the performance of the prototype Idylla™ MSI test, have been selected for presentation at the renowned European Society for Medical Oncology (ESMO) congress. The ESMO congress is considered the most influential annual meeting for oncology professionals in Europe and takes place between 19-23 October 2018 in Munich, Germany.

The first study[1] to be presented is an analysis of two prospective clinical trials[3] on anti-EGFR treatment in metastatic colorectal cancer (mCRC), and is a first in its kind to demonstrate the clinical impact of the liquid biopsy Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD). Results of this study showed that the Idylla™ liquid biopsy ctRAS-BRAF tests could predict treatment outcome in patients with mCRC by demonstrating that the presence of RAS and BRAF mutations in blood as determined by Idylla™ predicted anti-EGFR treatment benefit, both at baseline[4] as well as during treatment[5]. The study poster (545P) will be presented at ESMO on 21 October 2018 (12:45-13:45 CEST) by Dr Clara Montagut from Hospital del Mar, Barcelona (Spain).

The second study[2] revealed excellent performance of the prototype Idylla™ MSI test based on overall high concordance compared to other testing methods frequently used in today's clinical practice[6]. More specifically, a concordance of 98.7% was achieved with the Promega MSI analysis system and a concordance of 97.6% with immunohistochemical (IHC) analysis. In July 2018, the prototype Idylla™ MSI test was launched as a RUO[7] Idylla™ MSI Assay, which aims to provide information on the MSI status[8] (i.e. MSI-High or Microsatellite stable) of a tumor[9] in a rapid and easy way. The study poster (162P) will be presented at ESMO on 20 October 2018 (12:30-13:30 CEST) by Dr Bram De Craene from Biocartis.

Furthermore, Biocartis is organizing a workshop on its Idylla™ MSI Assay (RUO) with expert speakers from the Istituto Nazionale Tumori IRCCS – Fondazione Pascale, Naples (Italy) and the VIB-KU Leuven Center for Cancer Biology, Leuven (Belgium) at the ESMO conference on Monday 22 October 2018 (10:30-11:00 CEST, ICM-room 3-ground floor). The CE-marking of the Idylla™ MSI Assay for in vitro diagnostic use in colorectal cancer is anticipated in the first half of 2019.

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[1] Montagut et al., "Clinical impact of circulating tumor RAS and BRAF mutation dynamics in metastatic colorectal cancer patients treated with first-line chemotherapy plus anti-EGFR therapy: Combined analysis of two prospective clinical trials", to be presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.
[2] Decraene et al., "Detection of microsatellite instability (MSI) with a novel set of 7 Idylla™ biomarkers on colorectal cancer samples in a multi-center study", to be presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.
[3] PULSE and POSIBA studies performed by the GEMCAD group.
[4] Meaning at the start of the treatment.
[5] Patients with RAS and BRAF mutations in blood at baseline showed considerably shorter progression free survival (PFS) and overall survival (OS) compared to patients without such mutations, similar to standard of care RAS mutations determined on formalin fixed and paraffin-embedded (FFPE) tumor tissue. In addition, patients who acquired RAS or BRAF mutations during treatment displayed a much shorter PFS or OS compared to patients who remained free of mutations.
[6] Repeat length with this set of biomarkers was determined on 333 formalin fixed and paraffin-embedded (FFPE) colorectal cancer (CRC) samples using Idylla™ MSI Assay prototype cartridges, which allow a fully automated workflow including sample preparation, DNA amplification and automated repeat length calling. Consecutive analysis of 182 samples revealed a higher number of valid results for Promega (3.8%) and IHC (13.2%) compared to the prototype Idylla™ MSI Assay (2.2%). A neural network based algorithm was built on a large cohort of reference/patients samples (n>3000) obtained from different clinical sites (n>10) and different ethnic groups (n¼5). Three-hundred fourteen samples were characterized by means of the Promega MSI analysis system and 272 samples by means of MMR protein IHC staining. Approximately 30% of the samples included in the study were previously characterized to be MSI-H by either one of these methods.
[7] Research Use Only, not for use in diagnostic procedures.
[8] Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42.; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268.; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.
[9] Within approximately 150 minutes from just one slice of FFPE (formalin fixed, paraffin embedded) tumor tissue, without requiring a reference sample. MSI or 'microsatellite instability' is present in several tumor types including mCRC and is an independent factor that may predict a patient's response to certain immunotherapies. In a recent study in collaboration with Prof. Diether Lambrechts (VIB-KU Leuven, Belgium) presented at ASCO, the number of Idylla™ MSI Biomarkers were shown to be associated with total indel load and tumor mutational burden in endometrial tumors and in colorectal cancer (source: Zhao et al. J Clin Oncol 36, 2018 (suppl; abstr e15654).

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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 offers fifteen oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Forward-looking statements

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