

Biocartis receives grant for development of a fully automated MSI test

Test could be validated as prognostic test for colorectal cancer and predictive test for cancer immunotherapies

Mechelen, Belgium, 15 March 2017 - Biocartis Group NV ('the Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced it has received an approximately EUR 750k grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship¹. The grant supports Biocartis' ongoing microsatellite instability (MSI) and mutational load research program in collaboration with Prof. Diether Lambrechts (VIB – KU Leuven Center for Cancer Biology, Belgium), and aims to support the development of a fully automated MSI test on the Company's Idylla™ platform. The test will be based on a set of novel MSI markers² identified by Prof. Diether Lambrechts' laboratory, which were exclusively licensed to Biocartis from VIB in 2013.

MSI testing today: manual, lengthy and complex

Microsatellite instability is the result of errors in the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, resulting potentially in tumor growth. Today's commonly used techniques for MSI testing are expensive and rely on manual, lengthy and complex procedures involving amongst others PCR analysis followed by capillary electrophoresis using the Bethesda marker panel³. Because of these drawbacks, the potential of MSI testing is heavily underutilized. The novel MSI markers from VIB show 98.7% concordance with available MSI tests⁴. Furthermore, these markers enable testing based on Polymerase Chain Reaction (PCR) analysis only, and as such can be fully automated on Biocartis' Idylla™ platform.

Prognostic test for colorectal cancer

Today, MSI testing is included in several guidelines⁵ for all colorectal cancers (CRC) as CRC patients with an MSI-high status show a better prognosis compared to other CRC patients, and should consequently receive a different treatment (e.g. not to be given certain adjuvant chemotherapies³). The Idylla™ MSI Test under development will operate directly on a single slice of FFPE⁶ tissue from human CRC tissue. This without the need for a second slice used for control, as required for Bethesda method based testing. Thanks to this grant, Biocartis will be able to develop an easy, rapid and highly accurate standardized MSI test, available to a much larger patient population.

Prof. Diether Lambrechts, Director of the VIB – KU Leuven Center for Cancer Biology, commented: *"MSI testing can offer high clinical value to oncology treatments. The biomarkers that we identified at VIB in combination with the advantages of the Idylla™ platform would allow us to significantly lower barriers for MSI testing. We are excited to extend our collaboration with Biocartis into the immunotherapy space."*

Predictive test for cancer immunotherapies

Recent data⁷ have shown that advanced CRC patients with an MSI-high status respond particularly well to certain immunotherapies. As such, MSI may not only represent a prognostic marker, but may also predict a patient's response to certain immunotherapies which have demonstrated a positive impact on long term survival, especially in combination with targeted cancer therapies. Therefore, Biocartis will also collaborate with VIB to investigate MSI signatures in cancers other than CRC, the predictive nature of MSI markers for immunotherapy response, and mutational load signatures related to cancer immunotherapies.

Geert Maertens, Chief Scientific Officer of Biocartis, added: *"With Idylla™, MSI testing has the potential to open up to many more CRC patients with the aim to positively impact patient prognosis and patient*

1 Formerly known as IWT.

2 Zhao et al. (2014) eLife 3:e02725, 1-26.

3 The Bethesda MSI reference panel, established in 1997, consists of two mononucleotide loci (Big Adenine Tract or BAT-25 and BAT-26) and three dinucleotide loci (D2S123, D5S346 and D17S250). Using the Bethesda panel, cancers with instability at 2 or more of these loci were interpreted as MSI-high, and cancers with no instability at any of the five loci were considered Microsatellite Stable (MSS).

4 Claes et al. ASCO 2015.

5 NCCN Guidelines Colon Cancer version 2017.1; and, Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386–1422.

6 Formalin-fixed, paraffin-embedded.

7 Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. Cancer Discov. 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372, 2509-2520.

management. Furthermore, this grant will also support the road to a highly innovative MSI test for cancer immunotherapy, which we know will be of great value for the pharmaceutical industry. We are very grateful for this VLAIO project grant and look forward to continue to collaborate with Prof. Diether Lambrechts and his team."

Biocartis aims to launch its Idylla™ MSI Test in 2018.

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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 eight oncology tests and two infectious disease tests. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis_.

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