PRESS RELEASE

Biocartis strengthens biomarker portfolio for colorectal cancer

Exclusive license of recently detected EGFR resistance mutations

Mechelen, Belgium, 26 April 2016 - Biocartis (Euronext Brussels: BCART), an innovative molecular diagnostics company, today announces the exclusive licensing of a recently detected set of mutations in the Epidermal Growth Factor Receptor (EGFR)[1] that give resistance to anti-EGFR therapies in colorectal cancer. The aim is to integrate these biomarkers into molecular diagnostic tests for the Idylla™ platform, to enhance their ability to monitor therapy resistance in patients and thereby allowing physicians to optimise treatment selection.

The most frequently observed resistance mutation in this domain, EGFR S492R, was previously detected by Dr. Montagut and Dr. Albanell (Hospital del Mar, Barcelona, Spain) in 2012[2] and subsequently licensed to Biocartis for commercialisation on the Idylla™ platform[3]. Several additional mutations have now been identified in a collaborative effort between the laboratories of Dr. Montagut and Dr. Bardelli (University of Torino, Italy).

These new mutations were identified in the EGFR ectodomain[1] where anti-EGFR antibodies for the treatment of colorectal cancer prevent EGF binding, which causes the therapy not to work. The specific mutations were detected by comparing advanced preclinical methods with colorectal cancer patient data to identify these recently detected mechanisms of resistance (Arena et al.[4]). This completed package of anti-EGFR resistance mutations has now been licensed by the different inventors to Biocartis, with the aim to integrate these into molecular diagnostic tests for the Idylla™ platform. This will enable clinicians to rapidly select the right treatment, and as such optimise health outcome for the patient.

Dr. Clara Montagut, Hospital del Mar, Barcelona, Spain, stated: "*We are excited about our collaboration with Biocartis. Just a few years after discovery of the EGFR S492R resistance mutation in our lab, Biocartis has already developed and commercialised this mutation in its Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay. The addition of this recently detected set of resistance mutations will enable us to provide even better care for our colorectal cancer patients receiving anti-EGFR therapy. I am very much looking forward to the liquid biopsy version of this test, since monitoring and identifying resistance in our patients should allow us to switch to more effective therapies that are available in clinical trials.*"

Dr. Alberto Bardelli, University of Torino, Italy: "*The EGFR S492R mutation accounts for 16% of resistance to anti-EGFR therapies. These recently detected mutations explain resistance in an additional 5-10% of patients and preclinical models. Therefore, these EGFR ectodomain mutations are now established as one of the main and dominant mechanisms of resistance in >20% of colorectal cancer patients treated with anti-EGFR antibodies. Together with RAS mutations, they constitute the main markers that need to be monitored during such therapy. The Biocartis platform and tests are ideally suited for that purpose.*"

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For more information:

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[1] It concerns a new set of mutations in the EGFR ectodomain. While the commonly known EGFR mutations reside in the kinase domain of the EGFR receptor, which is located inside the cell, the EGFR ectodomain is the portion of the receptor located outside the cell, and represents the true receptor function where EGF binds, and where anti-EGFR antibodies for the treatment of colorectal cancer such as cetuximab and panitumumab engage the EGFR receptor and prevent EGF binding.
[2] Montagut et al. (2012) Identification of a mutation in the extracellular domain of the Epidermal Growth Factor Receptor conferring cetuximab resistance in colorectal cancer. Nat Med. 18: 221-223.
[3] Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay (Research Use Only, RUO)
[4] Arena et al. (2015) Emergence of multiple EGFR extracellular mutations during cetuximab treatment in colorectal cancer. Clin. Cancer Res. 21: 2157–2166.

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 infectious disease test on the market. More information on: www.biocartis.com.