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Biocartis launches CE-marked IVD test for lung cancer

Idylla™ EGFR Mutation Test is the only on market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines

Mechelen, Belgium, **13 June 2017 -** Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced the CE-marking of the Idylla™ EGFR Mutation Test, as such achieving an important milestone in Biocartis' lung cancer menu. The test is the only on market fully automated CE-IVD test that detects all relevant EGFR mutations according to international guidelines[1]. A comparison study[2] of the Idylla™ EGFR Mutation Test, of which an abstract was published at the 2017 ASCO Annual Meeting[3], compared the test with a commonly used EGFR pyrosequencing-based test[4]. This study concluded that the Idylla™ EGFR Mutation Test produced the results faster and easier, based on only one slice of tumor tissue[5]. As such this test has the potential to expand EGFR testing to more pathology laboratories in a reliable and fast manner.

Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types[6] and in total 85% of lung cancers are non-small cell lung cancers (NSCLC)[7]. The prevalence of EGFR mutations in NSCLC is 10-15% in Western and up to 50% in Asian patients[8]. Today, EGFR mutation testing is recommended in all patients with advanced NSCLC of a non-squamous subtype[9]. Current molecular testing of lung cancer samples however is still a very complex process. It can take up to several weeks[10] before results are generated, mainly because obtaining high quality tissue samples is difficult. Samples are often small, with a limited amount of available lung tumour tissue, leading to failure of test results in a significant number of cases. Moreover, many laboratories do not have the necessary infrastructure to perform complex molecular tests, resulting in laboratories sending out their samples to other testing facilities, causing long waiting times.

The Idylla™ EGFR Mutation Test, performed on Biocartis' Idylla™ platform, is designed to improve today's complex EGFR testing workflows. The test allows the detection of 51 EGFR mutations directly from only one slice of FFPE tissue, in contrast with traditional EGFR testing methods that often require up to six or more tumor slices. The test delivers results in approx. 2.5 hours with less than 2 minutes hands-on time. The clinical performance evaluation comparing the Idylla™ EGFR Mutation Test with a Polymerase Chain Reaction (PCR) based reference method showed an overall agreement of 96%[11] for mutations in the EGFR oncogene. A comparison study[2], of which an abstract was published at the 2017 ASCO Annual Meeting, compared the EGFR Mutation Test on the Idylla™ platform to a pyrosequencing method commonly used in clinical practice. This study concluded that the Idylla™ EGFR Mutation Test produced the results faster (sample-to-result time was about 180 minutes with about two minutes of hands-on time) than pyrosequencing (sample to result time about 12 hours) and easier.

Paola Valente, Strategic Marketing Director of Biocartis, commented: *"Many of our customer-laboratories have been waiting for the CE-IVD marking of our Idylla™ EGFR Mutation Test. EGFR testing on Idylla™ is easier and faster than other solutions available on the market today. As such, the Idylla™ EGFR Mutation Test will allow more wide-spread EGFR testing of lung cancer patients, without the need for specialized laboratory infrastructure."*

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[1] ESMO, CAP/IASLC/AMP, ASCO, NCCN.
[2] Ilie et al. "Optimization of EGFR mutation testing by the fully-automated qPCR-based Idylla on whole slide and biopsy tumor tissue of non-small cell lung cancer", J Clin Oncol 35, 2017 (suppl; abstr e20632), available at http://abstracts.asco.org/199/AbstView_199_191634.html, Abstract published at the 2017 ASCO Annual Meeting, 2-6 June 2017. Study is ongoing.
[3] The 2017 ASCO (American Society of Clinical Oncology) took place between 2-6 June 2017 in Chicago (US) and brought together more than 30,000 oncology professionals from around the world to discuss state-of-the-art treatment modalities, new therapies and ongoing controversies in the field.
[4] The study was performed on the Idylla™ EGFR Mutation Assay (RUO, Research Use Only). Comparison between the Biocartis' Idylla™ platform for the detection of EGFR mutations in archived formalin-fixed paraffin-embedded (FFPE) tumor samples with the results obtained by the TherascreenEGFR Pyro assay (Qiagen)-ISO 15189 accredited laboratory method.
[5] Formalin-fixed paraffin-embedded (FFPE).
[6] Navani et al., Lancet Respir Med (2015).
[7] American Cancer Society. Global Cancer Facts & Figures 2nd Edition (2011).
[8] Cooper et al., Molecular biology of lung cancer. J Thorac Dis (2013).
[9] NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017. Novello S. et al. Metastatic non-small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 2016.
[10] Neal I. Lindeman et al. Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors, Guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology (2014).
[11] Reference: Instructions for Use, Idylla™ EGFR Mutation Test.

The newly launched Idylla™ EGFR Mutation Test is an important addition to Biocartis' CE-marked IVD test menu, now consisting of five CE-marked IVD tests for melanoma, colorectal and lung cancer. A liquid biopsy version of this test, the Idylla™ ctEGFR Mutation Assay (Research Use Only or RUO), is under development and expected in H2 2017.

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