PRESS RELEASE

Biocartis launches advanced EGFR Mutation Assay detecting over 50 mutations

Important addition to Biocartis' core oncology menu now covering most known and used oncology biomarkers

Mechelen, Belgium, 21 June 2016 – Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), demonstrates that it continues to deliver on its promises with today's launch of the Idylla™ EGFR[1] Mutation Assay (RUO[2]). This advanced, fully automated molecular test is designed to detect over 50 EGFR mutations which commonly occur in lung cancer. Its extreme ease-of-use allows for testing, irrespective of location or laboratory expertise level. As such, this assay has the potential to enable more wide-spread testing of lung cancer specimens within reference centres and far beyond. The Idylla™ EGFR Mutation Assay is a key addition to Biocartis' menu, now consisting of seven assays, with five in the field of oncology, and covering most of the known and used oncology biomarkers.

Lung cancer and EGFR testing today: complex, lengthy and not accessible for everyone

Lung cancer is the most common cancer worldwide, accounting for 13% of all cancer types[3]. A total of 85% of lung cancers are non-small cell lung cancers (NSCLC)[4]. In these cancers, EGFR mutations occur in 10-15% of Western patients and in up to 50% of Asian patients[5]. The number of NSCLC cases where patients benefit from standard, non-targeted treatments, is limited. The introduction of targeted treatments that are aimed at the epidermal growth factor receptor (EGFR) pathway in NSCLC has begun to improve outcomes in patients with advanced NSCLC.

Molecular testing of lung cancer samples today is a very complex and often lengthy process: it can take up to several weeks[6] before results are generated. This is mainly related to the difficulty of obtaining high quality tissue samples. These are often small in size, with a limited amount of available lung tumour tissue, leading to failure of test results in 20-30% of the cases[7]. Finally, many laboratories do not have the necessary complex infrastructure, as different technologies are often needed to optimise EGFR detection in small samples. Consequently, laboratories often send out their samples to other testing facilities, resulting in long waiting times.

Fast and easy to use, based on a single tumour slice

With globally accessible molecular testing solutions as a key focus, Biocartis has developed the Idylla™ EGFR Mutation Assay, set up to run on Biocartis' Idylla™ platform and designed to improve current complex EGFR testing workflows. The assay is performed with a single slice of tumour[8] tissue. In addition, recent research studies with the Idylla™ EGFR Mutation Assay conducted by Prof. Troncone and Dr. Malapelle at the Institute Frederico II (Naples, Italy), demonstrated that very small cytological samples could also be used, and that the assay could rescue DNA leftovers inadequate for use with standard testing methods such as next generation sequencing, while generating a valid result in >97% of cases[9].

Simultaneous detection of over 50 different mutations

By integrating the latest selective amplification and multiplexing technologies, the Idylla™ EGFR Mutation Assay allows simultaneous detection of more than 50 different mutations, with minimal tumour sample or DNA input requirements[10] and without compromising on sensitivity[11]. The turnaround time of the assay is approximately 2.5 hours, from sample to result, with less than two minutes hands-on time. The Idylla™ technology has the potential to generate molecular testing results within one day, which greatly exceeds the current ESMO and international guidelines of seven days.

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[1] Epidermal Growth Factor Receptor.
[2] The Idylla™ EGFR Mutation Assay is intended for Research Use Only, not for diagnostic procedures. Not for sale in the USA and Canada.
[3] Navani et al. Lancet Respir Med (2015).
[4] American Cancer Society. Global cancer Facts & Figures 2nd Edition.
[5] Cooper et al. Molecular biology of lung cancer. J Thorac Dis (2013).
[6] 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).
[7] Estimated by Biocartis management.
[8] The analysis is done based on a slice of FFPE (formalin fixed paraffin embedded) tumour.
[9] De Luca et al. ASCO 2016.
[10] Minimum 1 x 5 µm FFPE tissue section with ≥ 10% tumour cells.
[11] An average sensitivity of ≤ 1 to ≤ 5% based on research data.

Geert Maertens, Chief Scientific Officer of Biocartis, commented: "Our seventh Idylla™ assay, the EGFR Mutation Assay, truly is a unique test from various perspectives. Being by far the easiest and fastest test for EGFR mutations available, it detects a broader range of mutations compared to standard tests and only requires a small amount of sample. We see great potential in Europe as well as in Asia where EGFR mutations in NSCLC occur in up to 50% of patients[12]. It is also a great solution both for large reference centres where this new assay is able to complement current workflows in a versatile, fast and cost-effective way, as well as for countries or regions where local accessibility to high precision EGFR testing is limited, or even non-existing. As such, we are convinced this assay will further boost the growth of our installed base of Idylla™ instruments across the globe."

Prof. Giancarlo Troncone, Department of Public Health, Anatomic Pathology Unit, University of Napoli Federico II School of Medicine (Napoli, Italy), stated: "Today, EGFR testing is a cumbersome process and it often takes several weeks before results are analysed. This may lead to the administration of anti-EGFR therapy as second-line therapy, which is less efficient than their use in first-line therapy. The Idylla™ EGFR Mutation Assay technology has the potential to change that: it is a cost-effective solution, ensuring accurate and fast detection of all relevant mutations."

A CE-marked IVD version of the Idylla™ EGFR Mutation Assay is planned for 2017. Biocartis also has a liquid biopsy version under 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. 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 five oncology tests and two tests for infectious disease on the market. More information: www.biocartis.com. Press Photo Library available here. Follow us at @Biocartis .

[12] Cooper et al. Molecular biology of lung cancer. J Thorac Dis (2013)