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ASTRAZENECA COMPARATIVE STUDY CONFIRMS BEST-IN-CLASS STATUS OF IDYLLA™ KRAS MUTATION DETECTION TECHNOLOGY

Mechelen, Belgium, **11 October 2016 -** Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a comparative study organised by AstraZeneca, a global biopharmaceutical company, where 12 different KRAS mutation detecting technologies, including Next-Generation Sequencing (NGS) and quantitative Polymerase Chain Reaction (PCR), were compared for the detection of KRAS mutations in lung cancer, using blinded samples. The study was presented yesterday at the renowned scientific oncology conference ESMO (European Society for Medical Oncology) in Copenhagen (Denmark). Results demonstrate superior levels of sensitivity of the Idylla™ KRAS technology to 10 out of the other 11 compared technologies, while at the same time it outperforms competition in ease-of-use and turnaround time. As such, this study confirms best-in-class status for the Idylla™ KRAS technology. A poster of the study can be found on the Biocartis website.

Blinded comparative study

The AstraZeneca study assessed 12 KRAS mutation detection technologies commonly used in today's molecular clinical diagnostic setting. The evaluated technologies included NGS (5) quantitative PCR (3, among which Idylla™), mass spectrometry (2), digital droplet PCR (1) and Sanger sequencing (1). The study focused on DNA samples that reflect input conditions typically encountered in clinical biopsies, in particular those of non-small-cell lung cancer[1] (NSCLC) patients, since mutations in the KRAS gene, besides the EGFR gene[2], are one of the most common drivers of NSCLC[3]. An important strength of the study is that the testing was performed on blinded samples, meaning that the different technology users were unaware of the true KRAS status of the samples.

Conclusion

The study showed a best-in-class performance of the Idylla™ KRAS technology, run on the Idylla™ platform:

- *Sensitivity*: Overall sensitivity of 96% across all mutant DNA samples and a specificity of 100% on normal DNA control samples. This sets the Idylla™ KRAS technology sensitivity on par with the best performing NGS technology and above the other NGS technologies (NGS technology-based sensitivity ranged in between 48%-100%). Compared to other PCR-based technologies, the Idylla™ KRAS technology outperformed as others ranged from 0%-92%; respectively 46%-52% for quantitative PCR, 58%-92% for mass spectrometry, 56% for digital droplet PCR and 0% for Sanger sequencing.
- *Ease-of-use*: Highest score for Idylla™ KRAS technology as a result of having the lowest number of manual handling steps in sample preparation (1 to 2 steps for Idylla™ versus 3 to > 20 for other technologies) and requiring lowest level of expertise (1 for Idylla™ versus 2-4 for others[4]).
- *Time-to-result*: Highest score for Idylla™ KRAS technology on total turn-around time (2 to 4 hours for Idylla™ versus 1 day to 3 weeks for the alternative approaches).

In general, the study concluded that the currently available KRAS mutation detection technologies and assays not only vary greatly in terms of technical and practical requirements, but also in performance on the tested samples given the observed sensitivity ranges. This again highlights the need for appropriate rapid, easy-to-use and high precision KRAS mutation testing suitable for use in *any* routine diagnostic lab setting.

Commenting on the announced performance study, Rudi Pauwels, Chief Executive Officer of Biocartis, said: "*We are extremely proud with the results of this study organized by a leading global pharmaceutical company like AstraZeneca. This is the broadest comparison study conducted by an external party on Idylla™ performance to date with respect to the number of different technologies applied on one sample set. It demonstrates that with the Idylla™ technology, we can truly combine the advantages of point-of-care testing in terms of ease-of-use and speed with the performance that one would expect from technologies used in reference*

[1] Roberts and Stinchcombe J Clin Oncol. 2013;31:1112–21.
[2] Today, in NSCLC, mainly testing for mutations in the EGFR gene is well established in routine clinical practice. (Source: Lindemann et al J Thorac Oncol. 2013;8(7):823–59.)
[3] Roberts and Stinchcombe J Clin Oncol. 2013;31:1112–21. The Idylla™ KRAS Mutation Test, performed on the Biocartis Idylla™ system, is an in vitro diagnostic test for the qualitative detection of 21 mutations in codons 12, 13, 59, 61, 117, 146 of the KRAS oncogene, intended for use in colorectal cancer.
[4] One being the lowest level of expertise and four the highest.

laboratories. As such, the Idylla™ technology has the potential to make rapid molecular diagnostic testing available in any routine diagnostic lab setting – large or small."

Publication PLOS One Journal

On 29 September 2016, another study[5] was published in the PLOS One Journal, a peer-reviewed open access scientific journal published by the Public Library of Science, on the performance of the Idylla™ KRAS Mutation Assay[6]. It concerns a multi-centered beta trial study at 12 different sites in Europe, each comparing the performance of the Idylla™ KRAS Mutation Assay on FFPE[7] tissue with their own reference methods (including NGS technology) used in clinical practice for detection of mutations in colorectal cancer. Among the 374 colorectal cancer FFPE samples tested in this study, the overall concordance between the Idylla™ KRAS Mutation Assay and the reference routine tests, including third method, was found to be 98.9%. Moreover, the Idylla™ KRAS Mutation Assay enabled detection of five additional KRAS-mutated samples not previously detected with reference methods. The publication is available online for download.

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

[5] Jérôme Solassol et al., "Multi-Center Evaluation of the Fully Automated PCR-Based Idylla™ KRAS Mutation Assay for Rapid KRAS Mutation Status Determination on Formalin-Fixed Paraffin-Embedded Tissue of Human Colorectal Cancer", available for download: http://journals.plos.org/plosone/article/asset?id=10.1371/journal.pone.0163444.PDF
[6] Performed on a Research Use Only version. A CE-marked IVD version of the Idylla™ KRAS Mutation Assay is available for use in colorectal cancer.
[7] FFPE: Formalin-fixed paraffin-embedded.