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Study Reviewing 2,500 Performed Idylla™ Tests Shows Generation of Valid Results in 98.1% of Cases and Outperformance over Reference Methods

Mechelen, Belgium, 27 June 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the recent publication of a study that reviewed the results of 18 performance studies[1] of Biocartis' fully automated molecular diagnostic platform Idylla™. Results showed a strong performance of Idylla™ compared to reference methods driven by a significantly lower invalid rate for Idylla™ tests and an overall high concordance in test results.

The performance review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy) and was published in the Journal of Clinical Pathology. It concerns a review of 18 original papers comparing the performance of the Idylla™ platform to other oncology molecular diagnostic methods commonly used in clinical practice today to determine biomarker status (BRAF, NRAS, KRAS and EGFR mutations) that drive frequently occurring cancers (i.e. melanoma, colorectal, lung, thyroid and pancreatic cancer[2]). The reviewed studies included 2,482 Idylla™ tests that were performed on tumor samples from 2,343 patients. For 2,378 samples, Idylla™ and reference method paired results were available for comparison.

Results showed that out of the nearly 2,500 Idylla™ tests, 98.1% of the tests generated a valid result. The 1.9% invalid results generated with Idylla™ is approx. 40% lower than the included reference methods, which showed invalid results in 3.1% of the cases. Furthermore, the study showed an excellent concordance rate of 94.8% between Idylla™ and the reference methods. Further testing of the discordant cases (5.2%) with a third method confirmed the Idylla™ result in more than half of the cases (54.8%).

Dr. Arnaud Uguen, MD PhD, Department of Pathology of the Brest University Hospital, Brest, France, commented: "*Data generated by the studies listed in our review demonstrate the high accuracy of the Idylla™ platform to test for actionable BRAF, NRAS, KRAS and EGFR mutations in different cancers, underlining the cost-effectiveness of Idylla™ testing compared to other molecular methods. Being rapid and easy to use, the Idylla™ platform can be used as a first-line diagnostic tool to reduce turnaround time, while a second-line more comprehensive Next Generation Sequencing (NGS) analysis can be carried out to provide additional information for the future management of patients.*"

The study can be consulted online here.

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[1] The Medline and Google Scholar databases were searched to retrieve studies addressing the Idylla™ system performance in comparison to other diagnostic methods. Only original papers were taken into account, excluding congress abstracts. Data analyzed included the number and types of samples, the specific Idylla™ cartridges used and the non-Idylla™ reference method. Special care was also taken to record discordant cases, focusing on the underlying reasons of disagreements between Idylla™ and non-Idylla™ methods.

[2] Overall, five studies were dedicated to colorectal cancer, four to lung cancer, four to melanoma, one to thyroid cancer, one to pancreatic cancer and three to different tumors including the aforementioned types as well as a few examples of other tumors. The studies included the following Idylla™ test cartridges used: Idylla™ BRAF Mutation Test (CE-IVD), Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay (RUO or Research Use Only), Idylla™ NRAS-BRAF Mutation Test (CE-IVD), Idylla™ KRAS Mutation Test (CE-IVD), Idylla™ NRAS Mutation Test (CE-IVD), Idylla™ EGFR Mutation Assay (RUO).

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

Forward-looking statements

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