PRESS RELEASE 23 September 2019, 07:00 CEST

Five Idylla™ Performance Studies to be Presented at 'European Society for Medical Oncology' congress

Mechelen, Belgium, 23 September 2019 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that five study posters on the performance of Idylla™ assays will be presented at the renowned European Society for Medical Oncology ('ESMO') Congress taking place between 27 September - 1 October 2019 in Barcelona (Spain). In general, all studies demonstrated excellent performance of Idylla™ compared to other methods, in combination with the ease of use and fast turnaround time of the Idylla™ platform. The studies included, amongst others, the Idylla™ MSI Assay (RUO[1]) and a prototype of the Idylla™ ctEFGR assay.

Of the five presented studies, four studies were performed by key opinion leaders in Europe:

- Matias-Guiu et al., '*Microsatellite Instability Detection in Colorectal Cancer: 44-center Comparison between the Idylla™ MSI Assay and Routine Molecular and Immunohistochemistry Tests of Formalin-Fixed Paraffin-Embedded Tissue*' (University of Lleida, Spain).
  This is a first-time international multi-centered study across 44 centers worldwide on 1,301 archival FFPE[2] colorectal cancer (CRC) tissue samples, demonstrating excellent performance of the Idylla™ MSI Assay (RUO[1]) compared to routine immunohistochemistry (IHC; overall concordance agreement of 96.6%) and molecular methods[3] (overall concordance agreement of 98.0%). Both the molecular methods and IHC had a higher invalid rate than the Idylla™ MSI Assay[4]. Furthermore, the study concluded several other Idylla™ MSI testing advantages, such as no need for a second control tissue sample, a simple workflow, short turnaround time, automated results interpretation and very limited hands-on work.
- Rutkowski et al., '*A Single Arm, Open Label, Phase II Multicenter Study to Assess the Detection of the BRAF V600 Mutation on cfDNA from Plasma in Patients with Advanced Melanoma'* (Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland). This study was led by Roche[5] for the treatment of BRAF mutant melanoma and supported by Biocartis.
- Bricogne et al., '*mCRC gene profiling using the Idylla™ platform*' (University College London, London Clinical Immunology, Oncology, UK).
- Fenizia et al., '*Tumor mutation burden and microsatellite instability in colorectal cancer'* (Centro Ricerche Oncologiche, Napoli, Italy).

The fifth presentation is a first performance study[6] conducted by Biocartis on the prototype liquid biopsy Idylla™ ctEFGR assay and included 64 NSCLC[7] samples. The study concluded that the prototype Idylla™ ctEGFR assay detected all mutations previously detected by the comparison method (Next-Generation Sequencing or NGS[8]). In 33 samples, NGS detected no mutation. The ctEGFR prototype assay[9] detected seven additional mutations in this cohort[10]. The launch of the fully automated Idylla™ ctEGFR Mutation Assay (RUO[1]) for liquid biopsy testing of EGFR mutations is expected in Q4 2019.

The abstract posters are now available for download on the ESMO website here and will be published during the poster sessions at the ESMO conference (Barcelona, Spain) between 27 September - 1 October 2019. More information can be found here.

[1] RUO = Research Use Only, not for use in diagnostic procedures
[2] FFPE = Formalin-fixed, paraffin-embedded
[3] Including the Bethesda Panel. The Bethesda MSI reference panel, established in 1997, consists of two mononucleotide loci (Big Adenine Tract or BAT-25 and BAT-26) and three dinucleotide loci (D2S123, D5S346 and D17S250). Using the Bethesda panel, cancers with instability at 2 or more of these loci were interpreted as MSI-high, and cancers with no instability at any of the five loci were considered Microsatellite Stable (MSS)
[4] The failure rate of the Idylla™ MSI Assay was 0.23%, while the molecular methods had a higher failure rate overall of 0.86% probably due to their use of a longer amplicon. IHC had a much higher failure rate of 4.37%, possibly related to interpretation difficulties of the results. Routine method failure rates might be an underestimation as the current analysis was done retrospectively on samples with known routine results
[5] Hoffmann-La Roche (Roche Holding AG)
[6] Reijans et al., 'Feasibility study of a ctEGFR prototype assay on the fully automated Idylla™ platform' (Biocartis, Mechelen, Belgium)
[7] Non-small cell lung cancer
[8] Sensitivity 2-5%
[9] The average turnaround time of a run was <2h 40 min and the hands-on time for the assay was <2 min
[10] Which were confirmed after retesting with the cobas EGFR Mutation Test v2

--- END ---

More information:

Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64

@Biocartis_ www.linkedin.com/Biocartis

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 is developing and marketing a continuously expanding test menu addressing key unmet clinical needs in oncology. This represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.