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New US Studies Demonstrate Idylla™ Allows Rapid First Assessment of Most Common EGFR Mutations Preceding Next-Generation Sequencing

Mechelen, Belgium, 2 February 2021 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of two recent studies by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ EGFR Mutation Assay (RUO[1]) as a rapid first-line testing method before using next-generation sequencing (NGS). Both studies conclude that Idylla™ EGFR testing enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS testing, which can be useful in cases where EGFR mutation results were negative and further testing is needed.

EGFR or 'Epidermal growth factor receptor' mutations are the second most common oncogenic driver in non-small cell lung cancer (NSCLC).

The first study[2] used a multi-test approach for rapid EGFR testing with the Idylla™ EGFR Mutation Assay (RUO[1]), followed by NGS. The study included 301 cytologic samples of which 218 were tested with the Idylla™ EGFR Mutation Assay (RUO), resulting in 24.3% (53/218 samples) that were EGFR-mutation positive. Concurrent NGS testing[3] showed 96.2% concordance and improved to 98.7% after incorporation of manual review criteria[4]. This study concluded that Idylla™ testing allows for rapid and accurate determination of EGFR status with low sample input and different sample types, without compromising subsequent more comprehensive NGS testing in cases where further testing is needed.

In the second study[5] with 1,249 samples, 98.57% (69/70) showed concordance with the reference methods. Of 1,179 clinical cases, 23.41% were EGFR positive by Idylla™. Concurrent NGS[6] testing showed concordance of 98.62% (788/799) and 98.50% (787/799) using MSKCC's in-house and Idylla™ analysis pipelines, respectively[7]. The study concluded that a first assessment of the most common EGFR mutations can be performed rapidly with the Idylla™ platform, while, in cases where further testing would be needed, comprehensive NGS testing remains possible for the vast majority of samples, with high success. The average turnaround time for the Idylla™ EGFR Mutation Assay (RUO), from receipt of material to report sign-out, was within three days, even accounting for extra steps of extraction and library preparation in small samples.

Herman Verrelst, Chief Executive Officer of Biocartis, reacted: "*In lung cancer, tissue is the issue as it is complex to obtain. For NGS, which is a more detailed sequencing technology frequently used in lung cancer, sample requirements are often very high. Many lung cancer samples therefore fail with NGS[8]. These studies indicate that Idylla™ and the Idylla™ EGFR Mutation Assay (RUO) is a sensitive and rapid technology that is well placed for first-line rapid and accurate determination of EGFR status, without excluding the possibility for subsequent NGS testing in cases where this is needed. Together with the Idylla™ GeneFusion Assay, which we plan to launch as a RUO assay in Q1 2021, these assays are expected to cover the majority of actionable lung cancer mutations and as such, have the potential to revolutionize lung cancer mutation testing by allowing actionable results for the clinician and patient within hours or days, instead of weeks.*"

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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

[1] RUO = Research Use Only, not for use in diagnostic procedures
[2] Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020
[3] On 96.4% of these samples
[4] To supplement automated calling, resulting in a diagnostic sensitivity of 95.6% (95% CI, 84.9% to 99.5%). In all, 9 % (14/159) of the cases tested by NGS had EGFR mutations not covered by the Idylla™ assay, primarily insertions in exon 19 and 20 and minor mutations co-occurring with canonical sensitizing mutations
[5] Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009
[6] Successfully performed on 94.9% (799/842) of the samples
[7] Discordances involved mutations missed by both assays associated with low tumor/low input. Incorporating a manual review algorithm to supplement automated calls improved accuracy from 98.62% to 99.37% and sensitivity from 94.68% to 97.58%
[8] De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMDpKZ7t9N&keytype=ref, 24 May 2018. More on https://investors.biocartis.com/sites/default/files/press-releases/2019/180525-PR-Idylla-EGFR_NGS_EN.pdf.

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, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

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