

30.05.2019 – 12:00 Uhr

Sysmex Inostics OncoBEAM(TM)-EGFR digital PCR liquid biopsy demonstrates two-fold higher detection of p.T790M mutations in 183 NSCLC patients in comparison study

Hamburg/Baltimore (ots) -

Sysmex Inostics announces the publication of clinical research conducted as part of the CIRculating CANcer (CIRCAN) Program at the Lyon Cancer Institute (Lyon, France) comparing the performance of Sysmex Inostics BEAMing (beads, emulsion, amplification, and magnetics) assay for EGFR resistance mutations (OncoBEAM-EGFR) to a next-generation sequencing assay (56G Oncology Panel from Swift Biosciences) in non-small cell lung cancer (NSCLC) patients with EGFR sensitizing mutations under first-line tyrosine kinase inhibitor (TKI) therapy.

The OncoBEAM-EGFR assay detected the p.T790M EGFR resistance mutation in twice as many patients (40/183 or 21.8% versus 20/183 or 10.9%), and those that were positive only on the OncoBEAM assay had a mean allele fraction of only 0.13%. This report also used the OncoBEAM-EGFR assay in a circulating tumor cell (CTC) spiking experiment, where the p.T790M mutation was detected in as few as 1.33 cells per mL of blood.

This research demonstrating sensitivity of 0.1% allele frequency in as little as 2 nanograms (2 ng) of input material was recently published in *Cancer Medicine* (Garcia and Couraud et al, <https://onlinelibrary.wiley.com/doi/full/10.1002/cam4.2244>) and was previously presented at the 2018 ESMO congress (<http://ots.de/P8G5O3>).

Principal investigator, Prof. Léa Payen from the Hospices Civils de Lyon commented on the results, "Given the high level of variability of tumor content in NSCLC patient plasma specimens and the great therapeutic utility of identifying an actionable EGFR mutation like T790M in a liquid biopsy specimen, it is of paramount importance to ensure mutation detectability at low allelic frequency. In our experience, plasma testing with OncoBEAM EGFR enabled us to detect the EGFR p.T790M mutation across a greater number of patients than NGS, representing a substantial proportion of patients that stand to benefit from targeted therapy."

Sysmex Inostics will highlight six posters and abstracts using OncoBEAM digital PCR and the new SafeSEQ NGS liquid biopsy technology at the upcoming American Society for Clinical Oncology conference and exhibition (booth 2098) in Chicago IL from May 31 to June 3, 2019.

About Sysmex Inostics

Sysmex Inostics, a subsidiary of Sysmex Corporation, is a molecular diagnostic company that is a pioneer in blood-based cell-free tumor DNA (ctDNA) mutation detection in oncology utilizing highly sensitive technologies such as OncoBEAM(TM) (digital PCR) and SafeSEQ (NGS). These technologies were initially developed by experts at the Johns Hopkins School of Medicine over a decade ago and this deep expertise in ctDNA analysis extends to the core of Sysmex Inostics' capabilities for technology development and implementation.

With more than 10 years' of experience in liquid biopsy Sysmex Inostics is a trusted partner to leading pharmaceutical companies, advancing their efforts to bring the most effective personalized cancer therapies to global markets, from discovery through companion diagnostics.

Sysmex Inostics' OncoBEAM(TM) and SafeSEQ services are readily available to support clinical trials and research in oncology. In addition, OncoBEAM(TM) tests are available through a CLIA certified laboratory for routine clinical analysis as well as distributed kit products in the EU.

Sysmex Inostics' headquarters and GCP Service Laboratory are located in Hamburg Germany; Sysmex Inostics' CLIA-certified and GCP Clinical Laboratory is located in Baltimore, Maryland. For more information refer to www.sysmex-inostics.com or email info@sysmex-inostics.com.

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