Sysmex Inostics GmbH

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Sysmex Inostics Presents Data at AACR Demonstrating SafeSEQ NGS Liquid Biopsy Delivers Equivalent Performance to the Extensively Clinically Validated OncoBEAM dPCR Technology for NSCLC Patients

Baltimore, MD, USA (ots) -

Sysmex Inostics, Inc., a global leader of the liquid biopsy revolution for oncology, is presenting the poster "Clinical evaluation of NGS-based liquid biopsy testing in non-small cell lung cancer (NSCLC) patients" at the 112th Annual Meeting of the American Association for Cancer Research on April 10, 2021, from 8:30 AM - 11:59 PM Eastern Daylight Time (EDT).

In a recent collaborative study, Johns Hopkins University School of Medicine and Sysmex Inostics' researchers showed that the next-generation sequencing (NGS)-based liquid biopsy SafeSEQ NSCLC panel delivers equivalent performance with broader genomic coverage than testing with OncoBEAM™ digital PCR (dPCR). OncoBEAM technology is widely considered a gold standard for high sensitivity molecular testing and continues to be one of the most sensitive dPCR approaches.

SafeSEQ technology demonstrates ultra-sensitive detection of low-frequency mutations, with a calling threshold of 5 mutant molecules (0.025% mutant allele frequency [MAF]) from whole blood. Concordance analysis of SafeSEQ and OncoBEAM results demonstrated an overall percent agreement of 99.6% for detection of mutations in EGFR, KRAS, and BRAF (>0.1% MAF).

The 5-year survival rate for metastatic NSCLC (mNSCLC) patients is relatively low; however, it has improved with the advent of targeted therapies and uptake of circulating tumor DNA (ctDNA) based technologies in recent years. In groundbreaking NSCLC clinical trials AURA and TIGER-X, patients positive for *EGFR* T790M detected in plasma by OncoBEAM had equivalent outcomes to patients positive by a tissue-based assay when treated with third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs), which have demonstrated potent activity against first-line EGFR TKI resistance mediated by *EGFR* T790M.

SafeSEQ NSCLC testing delivers broader genomic coverage than OncoBEAM, with the same ultra-sensitive detection for rare mutant molecules. Therefore, SafeSEQ is better suited to identify molecular mediators of treatment resistance to improve therapeutic strategies, delivering high-resolution monitoring of therapeutic efficacy, and enabling minimum residual disease (MRD) detection and recurrence surveillance for NSCLC patients.

Poster number LB053, "Clinical evaluation of NGS-based liquid biopsy genotyping in non-small cell lung cancer (NSCLC) patients," presented by Hillary Sloane, Associate Director of Medical & Scientific Affairs at Sysmex Inostics, will be available Saturday, April 10, 2021, from 8:30 AM - 11:59 PM EDT during the 112th Annual Meeting of the American Association for Cancer Research during Session PO.CL11.04 - Liquid Biopsies: Circulating DNA.

AURA Trial: Oxnard, GR, et al. J Clin Oncol **2016**, 34 (28), 3375–82.

TIGER-X Trial: Karlovich, C, et al. Clin Cancer Res **2016**, 22 (10), 2386–95.

About Sysmex Inostics

Sysmex Inostics, a Sysmex Corporation subsidiary, empowers discoveries in oncology by providing investigators cost-effective and ultra-sensitive quantitative liquid biopsy solutions SafeSEQ (NGS), and OncoBEAM™ (digital PCR).

Developed by experts at Johns Hopkins with the philosophy of "no molecule left behind," these technologies are optimized to ensure the detection of low-frequency mutant molecules (<0.05% MAF) with a high degree of specificity. Focused and flexible genomic coverage allows for superior sensitivity and reduced costs.

As pioneers in blood-based circulating tumor DNA (ctDNA) mutation detection, Sysmex Inostics has provided custom assays and CLIA-certified lab services to leading BioPharma companies over the last ten years to help develop therapeutics to extend lives and companion diagnostics to monitor progression, identify targetable resistance alterations, and detect minimal residual disease (MRD).

Sysmex Inostics' SafeSEQ and OncoBEAM services are readily available and customizable to support clinical trials and research in oncology. OncoBEAM™ tests are available through a CLIA-certified laboratory for routine clinical analysis and distributed kit products in the E.U.

Sysmex Inostics' European headquarters for research & development GCP laboratory testing are located in Hamburg, Germany; Sysmex Inostics' U.S. headquarters and 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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