Sysmex Inostics GmbH

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Sysmex Inostics' OncoBEAM(TM) platform demonstrates superior detection of clinically-relevant mutations for therapy selection and molecular monitoring for lung and colon cancers

Germany (ots) -

Data presented at the European Society of Medical Oncology (ESMO) 2018 meeting in Munich, Germany by three clinical oncology research groups demonstrate the importance of a highly sensitive test for detection of clinically-relevant mutations present in circulating tumor DNA (ctDNA) derived from a simple blood draw. Sysmex Inostics' ultra-high sensitivity OncoBEAM(TM) test was able to uncover mutations below the limits of detection for next-generation sequencing (NGS) as well as quantitative PCR (qPCR) tests, which represents a subset of patients for whom these lower-sensitivity methods could potentially miss important clinically actionable information.

In a study sponsored by the Cancer Genomics Group at Vall d'Hebron Institute of Oncology in Barcelona, investigators compared Sysmex Inostics' OncoBEAM(TM) RAS test to Biocartis' Idylla platform for detection of RAS mutations in plasma for patients with advanced-stage colorectal cancer. The OncoBEAM(TM) test uses BEAMing technology, an enhanced digital PCR method optimized for high sensitivity across different specimen types, while Idylla employs qPCR and is designed primarily for ease-of-use for mutational analysis of tissue and plasma specimens. Comparison of Idylla with reference results generated by the OncoBEAM(TM) assay, the current gold-standard for highly sensitive liquid biopsy, demonstrated inferior performance of Idylla with detection of KRAS mutations in only 81 out of 116 (70%) positive plasma samples. As expected, concordance with OncoBEAM(TM) substantially decreased at lower mutant allele frequency (MAF), which is representative of lower sensitivity achieved by qPCR techniques such as Idylla.

In another study, investigators at Hospices Civiles de Lyon evaluated Sysmex Inostics' OncoBEAM(TM) EGFR test as well as the 56G oncology NGS panel from Swift Biosciences for detection of the EGFR T790M resistance mutation present in advanced NSCLC patients on first-line EGFR tyrosine kinase inhibitor (TKI) therapy for whom progression was suspected. OncoBEAM(TM), which has pioneered acceptance of liquid testing for lung cancer in routine clinical practice, was able to detect T790M in a greater number of patients than the 56G oncology NGS panel. Notably, all positives detected by OncoBEAM(TM) but not 56G oncology NGS exhibited T790M present below 0.35% MAF, which is below the limit of detection for the NGS panel in this study (0.5% MAF) but in the range of reliable detection for the OncoBEAM(TM) test (LOD 0.02% MAF). As Dr. Lea Payen commented, "Resistance mutations such as T790M represent a significant therapeutic opportunity for NSCLC patients experiencing disease progression. However, detection T790M is often confounded due to its heterogeneous distribution throughout a patient's tumor burden which presents a diagnostic challenge for single-site tissue biopsies. Further, EGFR sensitizing and T790M mutations have been shown to be present at low allelic frequencies due to variable and sometimes limited ctDNA amounts in the plasma for NSCLC patients. The implementation of a highly sensitive assay like OncoBEAM(TM), which demonstrates reliable performance at low mutant allelic frequencies, is important in the context of NSCLC in order to reliably detect ctDNA in blood samples that may be missed by less sensitive approaches."

Building on the proven high sensitivity of the OncoBEAM(TM) EGFR test, the LungBEAM study conducted by researchers at 19 different hospitals across Spain and led by Prof. Pilar Garrido sought to evaluate the clinical value of longitudinal EGFR plasma testing in tissue-confirmed advanced NSCLC patients during first-line EGFR TKI therapy. The timing of emergence of the T790M resistance mutation was examined, as well as the dynamics of EGFR sensitizing mutations (L858R and exon 19 deletions) compared to radiological progression. Out of 60 patients who completed the study and showed clinical or radiological progression, 20 (33%) exhibited T790M present in plasma; for 13 of these patients, T790M was detected an average of 14 weeks prior to radiological progression. It was also found that clearance of EGFR sensitizing mutations 8 weeks after initiation of EGFR TKI therapy correlated with increased progression-free survival (40.3 weeks with clearance vs. 25.8 weeks without) and may be a favorable clinical indicator of PFS that can be easily measured early during therapy administration.

Together, these studies reinforce how the exquisite sensitivity of the OncoBEAM(TM) platform which enables detection of the greatest number of positive patients overall can deliver unique clinical value. A highly sensitive assay is especially important for timely detection of mutations that can be monitored in real time as surrogate biomarkers of disease burden. "The demonstrated high sensitivity of OncoBEAM(TM) is ideal not only to maximize detection of known therapeutic indications, but also to explore potential clinical uses of ctDNA to monitor disease evolution at much higher resolution that is currently possible through radiographic imaging," commented Dr. Pilar Garrido, lead investigator for the LungBEAM study. "At a time when many different technologies and products are available for molecular oncology, it has become increasingly important for researchers and clinicians to select the best option to answer the specific question at hand."

Presentation Details (all times local)

- Saturday, October 20th,12:30, Biomarkers, 100P: Comparison of
  OncoBEAM and NGS methods to detect plasma EGFR T790M mutations at

progression of NSCLC.

- Saturday, October 20th, 12:30, Biomarkers, 121P: LungBEAM: A prospective multicenter trial to monitor EGFR mutations using BEAMing technology in Stage IV NSCLC patients.

- Sunday, October 21st, 13:05, Gastrointestinal tumors - colorectal, 550P: Evaluation of the sensitivity of RAS mutation detection of the Idylla platform in comparison to the OncoBEAM RAS CRC assay.

About OncoBEAM(TM)

Sysmex Inostics' highly sensitive OncoBEAM(TM) services allow for molecular genetic analysis of cell-free tumor DNA from blood or plasma, delivering an individualized approach to complement treatment decision-making in oncology. Based on the highly sensitive BEAMing technology developed at the Johns Hopkins University School of Medicine, OncoBEAM(TM) testing is able to provide multiplex hotspot mutation analysis for the accurate and reliable detection of rare mutant molecules of tumor DNA from blood samples of patients with cancer. Due to its minimal-invasive nature, OncoBEAM(TM) delivers new possibilities for cancer management while minimizing costs and risks inherent with tissue biopsies. The OncoBEAM(TM) assays target a wide variety of clinically actionable genetic mutations in various cancers like melanoma, colorectal, breast and lung cancer, delivering information in real-time to support therapy selection, detection of emergent mutations and assessment of drug response. In the US, OncoBEAM(TM) tests are available as GCP and CLIA services. OncoBEAM(TM) RAS CRC CE IVD kit is available in EU.

About Sysmex Inostics

Sysmex Inostics, a subsidiary of Sysmex Corporation, is a molecular diagnostic company whose core competency is mutation detection utilizing highly sensitive technologies such as BEAMing and Plasma Safe-Sequencing. Sysmex Inostics is a trusted partner to leading pharmaceutical companies, advancing their efforts to bring the most effective personalized cancer therapies to global markets.

With BEAMing and Plasma Safe-Sequencing (SafeSeq) being some of the most sensitive technologies available today for the detection of tumor-specific somatic mutations in blood samples, Sysmex Inostics' services are readily available to support clinical trials and research in oncology. In addition, OncoBEAM(TM) tests are available today through a CLIA-certified laboratory for routine clinical analysis.

Sysmex Inostics' headquarters and GCP Service Laboratory are located in Hamburg Germany; Sysmex Inostics' Commercial Offices and CLIA-certified and GCP Clinical Laboratory is located in Baltimore, Maryland. For more information on Plasma Safe-Sequencing and OncoBEAM(TM) blood testing, please visit www.sysmex-inostics.com or email info@sysmex-inostics.com.

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