Sysmex Inostics GmbH

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Sysmex Inostics' OncoBEAM(TM) liquid biopsy technology demonstrates utility for clinical management of melanoma patients undergoing treatment with targeted therapy and immune checkpoint inhibitors

Germany (ots) -

Sysmex Inostics, a pioneer in blood-based circulating tumor DNA (ctDNA) analysis and molecular diagnostics for oncology, is pleased to announce publication of a study in the Journal of Molecular Oncology highlighting the important clinical value of blood-based ctDNA mutation testing to complement standard-of-care management of patients with advanced melanoma. Investigators at Johns Hopkins University School of Medicine utilized Sysmex Inostics' CLIA-certified OncoBEAM liquid biopsy tests to examine the clinical utility of ctDNA measurements as an adjunct to radiographic imaging for monitoring disease activity and to inform clinical decision-making in patients undergoing treatment with targeted therapy or immune checkpoint inhibitors. This investigation represents one of the first to provide direct evidence of the impact of ctDNA on interpretation of radiographic data and clinical outcomes and furthers the extensive clinical validation of OncoBEAM, which is the current gold-standard for liquid biopsy testing.

Advanced melanoma is challenging to treat, with overall 5-year survival rates of around 20%, meaning only 1 in 5 patients will survive for 5 years after diagnosis. Although current targeted and immune-based therapies have demonstrated remarkable anti-tumor ef?cacy in patients with advanced melanoma, numerous challenges exist towards ensuring patients receive the most highly-effective treatment. Currently, tissue testing is preferred for detection of actionable mutations; however, it is known that false negative calls may result when the tissue sample testing fails to capture genomic profiles of interest, sometimes due to molecular heterogeneity. Additionally, radiographic imaging, which includes CT and PET scans, is the current standard-of-care for evaluation of therapeutic response. However, several clinical research groups have previously demonstrated difficulties associated with interpreting imaging in patients undergoing treatment with immunotherapies as tumors may appear to grow before eventually regressing. Furthermore, microscopic occult disease that can drive tumor progression may go undetected by even the most sensitive radiographic techniques. Together, the result is that current standard-of-care practices may, in some cases, fail to yield vital clinical information.

With these clinical challenges in mind, investigators at the Johns Hopkins University School of Medicine led by Drs. Evan Lipson, Medical Oncology, and Steven Rowe, Radiological Sciences, sought to examine the performance of OncoBEAM by comparing the agreement of plasma mutation testing with that of standard-of-care tumor tissue mutation testing. All plasma mutation analysis was performed with the OncoBEAM BRAF and NRAS assay validated in Sysmex Inostics' CLIA-certified laboratory (Baltimore, MD). Fifty-five patients were evaluated, with OncoBEAM demonstrating a sensitivity and specificity for NRAS and BRAF mutation detection in plasma of 86.7% and 100%, respectively. In addition to high overall agreement with tissue testing, the clinical value of ctDNA was underscored by two patients for whom tissue analysis did not detect a BRAF V600E mutation that was successfully detected in plasma. Based on the ctDNA findings, both patients were treated with BRAF/MEK-targeted therapy; each patient experienced a partial response to treatment (RECIST v1.1).

Drs. Lipson and Rowe also investigated the clinical utility of ctDNA to assist with interpretation of radiographic data in patients with advanced melanoma receiving either targeted therapy or immune checkpoint inhibitor therapy. ctDNA levels were serially monitored in 30 patients and results were correlated with interpretation of radiographic imaging. The investigators discovered that in a subset of those patients, ctDNA signaled disease progression an average of 21 weeks earlier than did radiographic imaging. These results have important implications for the clinical management of patients receiving immunotherapy and demonstrate the value of performing ctDNA testing for better resolution of tumor activity when performed alongside routine imaging and clinical assessments.

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 minimally 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 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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