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Sysmex Inostics OncoBEAM(TM) circulating tumor DNA technology demonstrates superior response prediction for advanced pancreatic cancer over standard-of-care protein biomarkers

Germany (ots) -

Recent data published in Annals of Oncology (https://academic.oup.com/annonc/advance-article/doi/10.1093/annonc/mdy417/5139593) from a study conducted by Sysmex Inostics and University of Munich indicate that circulating tumor DNA (ctDNA) may offer clinicians higher-resolution information for response prediction and therapy monitoring for advanced pancreatic cancer patients compared to current established protein biomarkers. Sysmex Inostics' gold-standard OncoBEAM(TM) liquid biopsy technology was used for highly sensitive, quantitative determination of ctDNA levels in blood samples serially collected from advanced pancreatic cancer patients receiving chemotherapy. Not only was the presence of detectable ctDNA in the blood significantly correlated with adverse clinical outcomes, but changes in ctDNA levels in response to therapy were both more pronounced and rapid than changes in established protein biomarkers, suggesting potential clinical benefit of serial ctDNA testing for improved patient care.

The survival rate for advanced pancreatic cancer remains poor despite intensified therapeutic regimens, with median overall survival still less than one year. While development of novel therapies would be accelerated by robust predictive and prognostic biomarkers, thus far carbohydrate antigen 19-9 (CA 19-9), which was originally characterized in 1979, is the only biomarker recommended for routine clinical use. However, given recent advancements in highly sensitive liquid biopsy as well as increased understanding of the relationship between ctDNA and disease progression, ctDNA testing may offer advantages over CA 19-9 and other protein biomarkers such as carcinoembryonic antigen (CEA) and cytokeratin-19 fragments (CYFRA 21-1). While protein biomarkers are not tumor-specific and can be elevated in patients without cancer, ctDNA delivers unique specificity as a real-time tumor biomarker. Because mutations affecting the KRAS gene are known to be present in approximately 90% of pancreatic cancers, highly sensitive detection focused on KRAS is ideal for investigation of the predictive and prognostic power of ctDNA in pancreatic cancer.

Sysmex Inostics's OncoBEAM(TM) platform, which is based on BEAMing technology developed at Johns Hopkins University and is the current gold-standard for highly sensitive detection of clinically-relevant mutations, was used in this study to determine ctDNA levels in blood specimens collected from advanced pancreatic cancer patients. Out of 28 patients with metastatic disease, 22 (79%) had a baseline KRAS mutation detectable in the blood, which was significantly correlated with both adverse progression-free survival (PFS) as well as overall survival (OS). Additionally, when serial blood samples were evaluated up until tumor progression, an increase in KRAS-mutant ctDNA indicated disease progression with a sensitivity of 83%, and no false positives (100% specificity). By contrast, CEA demonstrated only 52% sensitivity and 86% specificity for identification of disease progression, while CA 19-9 showed inferior sensitivity across multiple different diagnostic cut-offs.

These results suggest utility of ctDNA for evaluation of therapeutic response for pancreatic cancer that exceeds the resolution of current established protein-based markers. The ability to correlate changes in ctDNA with clinical response depends heavily on the capabilities of the technology used. Importantly, the breadth of dynamic range of ctDNA discrimination and especially accuracy at the lower limit of detection are key and are both native features of BEAMing. As Dr. Stefan Holdenrieder, senior investigator for the study commented, "The extremely high sensitivity of OncoBEAM(TM) is especially useful for serial testing of mutations which may be initially present at very low levels in the blood and may also decrease in frequency in response to therapeutic intervention. Accurate detection well below 1% mutant allele frequency, and even below 0.1%, allows the most thorough evaluation of disease response by minimizing the chances of false negative calls." Dr. Holdenrieder added, "As evidence continues to accumulate supporting the integration of ctDNA into routine clinical practice for therapeutic monitoring and response prediction, use of a highly sensitive test such as OncoBEAM(TM) will then translate directly into the most reliable results for patients."

Publication Details

Kruger, S. et al. Repeated mutKRAS ctDNA measurements represent a novel and promising tool for early response prediction and therapy monitoring in advanced pancreatic cancer. Ann Oncol. Off. J. Eur. Soc. Med. Oncol. (2018). https://doi.org/10.1093/annonc/mdy417

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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