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Sysmex Inostics' Liquid Biopsy Testing Benefits Metastatic Pancreatic Cancer Patient Management

Baltimore, MD (ots) -

Sysmex Inostics, Inc., a global leader and pioneer in blood-based circulating cell-free tumor DNA (ctDNA) analysis for oncology, today announces the publication of a clinical study investigating the utility of cfDNA-based markers using the highly sensitive OncoBEAM RAS assay, an enhanced digital PCR test optimized for high sensitivity blood-based mutation detection, as a prognostic tool in patients with metastatic pancreatic ductal adenocarcinoma (PDAC).

Pancreatic cancer is the fourth leading cause of cancer related death worldwide. Moreover, PDAC accounts for 90% of all pancreatic cancers with an overall 5-year survival of less than 8%, the lowest survival rate of all cancers. Patients diagnosed with PDAC suffer from a poor prognosis which is attributed to diagnosis at an advanced stage, due to late onset of symptoms and lack of reliable biomarkers for early detection. Moreover, most patients with late stage disease exhibit resistance to available therapy modalities.

The primary initiating genetic event for PDAC is a KRAS mutation, occurring in 94% of pancreatic ductal tumors. KRAS mutational status is typically analyzed in tumor tissue but obtaining biopsy specimens from pancreatic lesions - especially during chemotherapy treatment - may be difficult and requires invasive procedures. Tumor tissue for biomarker testing is only available at diagnosis and is not feasible to access during treatment. CfDNA-based liquid biopsy analysis of KRAS mutations using OncoBEAM technology represents a minimally-invasive tool to measure levels of circulating KRAS mutations to assist in the prognosis determination and management of PDAC patients.

The study published by investigators at the University of Córdoba, Spain indicates that the dynamics of circulating RAS mutations may better correlate with patient outcomes and survival compared with CA19-9 protein blood-based marker testing. CA19-9 is usually found in higher concentrations in pancreatic cancer, however, it is not a tumor specific biomarker and can be elevated for reasons unrelated to cancer. In this comparative analysis, a significant correlation was found between the increase in RAS mutation levels detected in plasma by the OncoBEAM RAS test ($r = 0.65$, $p = 0.02$), but not in CA19-9 ($r = 0.09$, $p = 0.78$) and survival time. Overall, greater increases in levels circulating KRAS mutation during patient monitoring predicted shorter survival time, with researchers noting that KRAS mutant cfDNA shows great promise as real-time biomarker of tumor response.

Lead author Dr. Toledano-Fonseca of Maimónides Biomedical Research Institute of Córdoba (IMIBIC), said, "Remarkably, sensitive plasma KRAS mutation testing using OncoBEAM alongside of CA19-9 and fragmentation analysis greatly helped prognosis stratification of metastatic PDAC patients. Our results support KRAS MAF as a valuable complementary tool for monitoring the response to chemotherapy treatment in metastatic PDAC patients."

The publication, titled "Circulating Cell-Free DNA-Based Liquid Biopsy Markers for the Non-Invasive Prognosis and Monitoring of Metastatic Pancreatic Cancer" was published in *Cancers*, July 1, 2020, by Marta Toledano-Fonseca et al.: <https://www.mdpi.com/2072-6694/12/7/1754>.

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™ (digital PCR) and SafeSEQ (NGS). These technologies were initially developed by experts at the Johns Hopkins School of Medicine over a decade ago. 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™ and SafeSEQ services are readily available to support clinical trials and research in oncology. In addition, OncoBEAM™ tests are available through a CLIA-certified laboratory for routine clinical analysis as well as distributed kit products in the EU.

Sysmex Inostics' European headquarters for research & development GCP laboratory testing are located in Hamburg Germany; Sysmex Inostics' US headquarters and CLIA-certified and GCP Clinical Laboratory is located in Baltimore, Maryland.

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