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Sysmex Inostics launches two NGS-based liquid biopsy panels for cancer therapy drug development

Maryland (ots) -

Sysmex Inostics announces the availability of the SafeSEQ Breast Cancer and Head and Neck Cancer Panels along with the SafeSEQ Rapid Custom Development program for circulating tumor DNA (ctDNA) analysis. SafeSEQ is a next-generation sequencing (NGS)-based approach that delivers sensitivity comparable to the clinically validated OncoBEAM platform for rare mutant molecule detection, with sensitivity down to five mutant molecules amongst ten thousand wildtype copies, or 0.05% mutant allele frequency (MAF).

The SafeSEQ Breast Cancer Panel tests for mutations affecting the PIK3CA, ESR1, TP53, ERBB2, AKT1 and KRAS genes in ER-positive, HER2-negative breast cancer samples. Alterations in these genes can guide an oncologist's selection of appropriate therapy, clinical trial enrollment, or indicate mechanisms of therapy resistance. The SafeSEQ Breast cancer panel provides unparalleled highly sensitive detection of mutant ctDNA and is thus also well suited for disease monitoring in order to assess treatment response, minimal residual disease and molecular relapse.

The SafeSEQ Head and Neck Cancer Panel tests for mutations in the genes PIK3CA, CDKN2A, HRAS and TP53. Although head and neck squamous cell carcinoma (HNSCC) affects approximately 600,000 globally, molecular testing is not routinely performed, and a number of molecular alterations in these genes are actively being pursued as therapeutic targets. A primary challenge in HNSCC is that many patients exhibit low levels of ctDNA with the vast majority having a MAF below 1%. Below this level, many liquid biopsy tests have demonstrated poor performance. Sysmex Inostics has demonstrated reliable, high-sensitivity detection well below this level with detection of as few as five mutant molecules in a background of ten thousand wildtype ones, or a MAF of 0.05%.

"In the fast-growing field of liquid biopsy for cancer therapy selection and monitoring of recurrent disease, assay sensitivity is paramount" says Dr. Frank Holtrup, Director of R&D at Sysmex Inostics. "We have worked hard to optimize every step of the assay process, from sample collection through processing and bioinformatics to ensure industry-leading sensitivity down to single mutant molecules for our SafeSEQ liquid biopsy tests."

In addition to the standard SafeSEQ panels, Sysmex Inostics offers a Rapid Custom Development program, where client-selected target genes and mutations can be assembled into highly sensitive fit-for-purpose assays with customer-selected levels of analytical and clinical validation.

At the European Society of Molecular Oncology in Barcelona, Spain September 27 - October 2, 2019 Sysmex Inostics will be exhibiting at Booth 250 in Hall 2, and several posters will demonstrate the utility of Sysmex Inostics enhanced digital PCR OncoBEAM and NGS-based SafeSEQ technology for liquid biopsy, including the following:

"Clinical relevance of circulating tumor (ct)DNA genotyping for first line cetuximab-based treatment monitoring in metastatic colorectal cancer (mCRC): a prospective multicentric study" (Dr. Joana Vidal Barrull, poster 625P, 29 Sept 2019 1200). "Sequential RAS mutation testing in cfDNA in RAS wild type (wt) metastatic colorectal cancer (mCRC) patients (pt) treated with panitumumab (P) and chemotherapy (CT) in first line (1L) PERSEIDA study" (Dr. Manuel Valladares-Ayerbes, poster 531PD, 29 Sept 2019 1200).

"Blood-based testing of mutations in patients with Head and neck squamous cell carcinoma (HNSCC) using highly sensitive SafeSEQ technology" (Dr. Florentia Fostira, poster 1158P, 30 Sept 2019 1200).

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

Sysmex Inostics' headquarters and GCP Service Laboratory are located in Hamburg Germany; Sysmex Inostics' 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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