Sysmex Inostics GmbH

16.12.2019 – 12:00 Uhr

Sysmex Inostics announces first results of tissue-independent liquid biopsy for early stage breast cancer mutation characterization and monitoring using ultra-sensitive SafeSEQ technology

Maryland (ots) -

New data presented by Dr. Ben Ho Park, Professor of Medicine and Director of Precision Oncology at Vanderbilt University and colleagues at the recent San Antonio Breast Cancer Symposium (SABCS) in San Antonio, Texas demonstrated a potential utility for monitoring tumor-specific mutations (TSMs) in the circulation of early stage triple-negative breast cancer patients. The investigators utilized Sysmex Inostics' highly sensitive SafeSEQ technology to detect rare variants down to 0.05% mutant allele fraction (MAF) to explore the rate of detection of ctDNA variants independent of the need for a tissue biopsy.

This initial data was generated as a pilot investigation as part of the PREDICT DNA trial ("Pathologic Response Evaluation and Detection In Circulating Tumor DNA"), the first prospective, multi-center study designed to verify cell-free circulating tumor DNA (ctDNA) as a biomarker for treatment response and recurrence in early stage breast cancer, with the primary aim of determining the negative predictive value of a negative ctDNA result after neoadjuvant therapy for the achievement of pathologic complete response. Essentially the trial measures whether patients who undergo neoadjuvant chemotherapy to treat tumors prior to surgery still have ctDNA in their blood after the therapy but before surgery. Dr. Park shared "We give chemotherapy to early stage breast cancer patients and probably 70 percent of those patients don't need it, but we generally can't define who has micro-metastatic disease and who doesn't." The PREDICT DNA trial is aiming to understand whether ultrasensitive next-generation sequencing with a SafeSEQ targeted cancer mutation panel can identify and monitor ctDNA of early-stage breast cancer patients to more precisely administer neoadjuvant therapy and surgery in newly diagnosed patients.

A total of 228 patients with Stage II and III triple-negative or HER2-positive breast cancer have been enrolled at 22 sites, of which 77 with matched pre- and post-neoadjuvant therapy samples were available at the time of the pilot study. Using SafeSEQ, tumor-specific mutations were identified in 48% (37/77) of the pre therapy samples, of which 89% had detectable plasma TP53 mutations, 11% had PIK3CA mutations, and 11% had co-occurring TP53 and PIK3CA mutations. A cohort of patient plasma specimens underwent orthogonal testing with OncoBEAM digital PCR technology, with 100% concordance of results with SafeSEQ.

The authors of the study concluded that SafeSEQ's ultrasensitive detection of ctDNA has 'significant clinical implications as an affordable and non-invasive first-pass assay in patients with sparse tumor biopsy tissue'. This preliminary data also demonstrates clinical feasibility of identifying tumor-specific mutations in individuals using minimally-invasive liquid biopsy before neoadjuvant treatment for personalized disease response monitoring without the need for biopsy tissue for NGS analysis.

"There is a paramount need for prospective studies using liquid biopsy" said Dr. Ben Ho Park, Professor of Medicine and Director of Precision Oncology, Vanderbilt University Medical Center. "These exciting preliminary results from the PREDICT DNA Trial represent an important first step in understanding the role of liquid biopsy testing for the management of early stage breast cancer and helping the medical community map out a path to make precision medicine a reality for patients across the continuum of care."

Presentation Details: Saturday 14 December 2019 7am - 9am, Poster Session 6, P6-10-05

Hunter, N. et al (2019) Pathologic Response Evaluation and Detection In Circulating Tumor DNA (PREDICT DNA): Initial results piloting a tissue-biopsy independent method of identifying and monitoring tumor-specific mutations in early stage breast cancer: TBCRC 040 Presented at the San Antonio Breast Cancer Symposium in San Antonio, Texas. ClinicalTrials.gov Identifier: NCT02743910

This work supported by the Translational Breast Cancer Research Consortium.

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.

Contact:

Contact:

Sysmex Inostics
PressRelease
Phone: +49-(0)-40-3259070
Mail: info@sysmex-Inostics.com