Sysmex Inostics GmbH

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Sysmex Inostics publishes first feasibility study of NGS-based liquid biopsy to complement early breast cancer screening by imaging

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Using Sysmex Inostics' novel SafeSEQ next-generation sequencing cell-free DNA technology, investigators from the Biomedical Research Institute of Malaga [(IBIMA)-CIMES-UMA, Malaga Spain] and collaborators have published the first pilot study to examine the use of a non-invasive liquid biopsy in early diagnosis of breast cancer. This study was unique in that the ctDNA analyses was performed before any invasive diagnostic procedure or treatment.

The SafeSEQ liquid biopsy technology has shown sensitivity down to five mutant molecules in a background of ten thousand normal ones (or 0.05% mutant allele frequency also known as MAF). Utilizing the genes TP53 and PIK3CA, which are commonly mutated in breast cancer, investigators compared the results of traditional standard-of-care tissue biopsy with those of liquid biopsy to determine the degree to which a highly sensitive assay might complement clinical assessment of disease. Of the 13 mutations detected in 10 of the primary breast cancer patients (out of a total of 29 samples) 8 mutations had a variant allele frequency less than 0.39%.

Comparing tissue to liquid biopsy, eight patients had detectable mutations in ctDNA with concordant results between tissue and plasma. Liquid biopsy testing with SafeSEQ detected an additional three patients with ctDNA mutations that were not present in the tissue. The breast cancer samples with detected ctDNA biomarkers were significantly associated with a lower patient age, a higher tumor size, and higher imaging score (indicating higher likelihood of neoplastic disease).

"We have shown in this study how important a sensitive technology is for early detection of breast cancer, as trace amounts of circulating tumor DNA may be lost by the detection method leading to false-negative results", said Dr. Emilio Alba, senior author of the Biomedical Research Institute of Malaga. "Studies of this kind have not been attempted before due to limitations of the technology, and it is great to see Sysmex Inostics leading the path forward for early detection."

The publication "Detection of TP53 and PIK3CA mutations in circulating tumor DNA using Next-Generation Sequencing in the screening process for early breast cancer diagnosis", was published online in the Journal of Clinical Medicine in August of 2019. https://doi.org/10.3390/jcm8081183

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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