Sysmex Inostics GmbH

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# Sysmex-Inostics Colorectal Cancer Blood-Based OncoBEAMTM RAS CE-IVD Test Shows Concordance with Standard of Care Tissue-Based RAS Testing

*Baltimore, Maryland (ots) -*

Sysmex-Inostics, Inc., a global leader and pioneer in blood-based circulating tumor DNA (ctDNA) analysis for oncology, today announces the publication of a clinical study evaluating the performance of plasma RAS mutation testing with OncoBEAM RAS CRC as compared to standard of care tissue-based RAS testing in the United Kingdom (UK).

OncoBEAM RAS CRC is a CE-IVD test that uses BEAMing technology, an enhanced digital PCR method optimized for high sensitivity blood-based mutation detection for metastatic colorectal cancer (mCRC) patients. This is the first study of its kind in the UK with confirmatory testing performed across laboratories certified to run the OnocBEAM RAS CRC test. Investigators also utilized the highly sensitive nature of OncoBEAM testing to also explore the clinical value of detecting changes in plasma RAS mutation status in patients treated with anti-EGFR antibody therapy.

The overall percent agreement between the OncoBEAM assay and tissue-based testing for RAS mutations was 86.0% (86/100), with a 100% reproducibility of test results between three labs located in the UK, Germany, and Japan. This demonstrates that blood-based testing with an appropriate and well validated assay can serve as an alternative to tissue-based testing and can improve access to precision medicine globally.

Colorectal cancer (CRC) continues to be one of the leading causes of cancer-related deaths globally. Anti-EGFR monoclonal antibodies have demonstrated significant improvements in survival of patients with wild-type RAS tumors mCRC. However, tissue-based biomarker testing has been shown to present several challenges, such as tumor molecular heterogeneity, poor tissue quality, and logistical issues, which can contribute to delays in treatment initiation. Importantly, as patients undergo treatment with targeted therapies, insight into changing tumor molecular dynamics would require repeat tissue biopsies, which is not practical in routine clinical management. Since mCRC patients already undergo regular blood draws throughout treatment; testing with the OncoBEAM RAS assay can deliver valuable insights into tumor response.

The ability to draw serial blood samples and perform OncoBEAM ctDNA longitudinal analyses of RAS mutant allelic fraction (MAF) variation before and during anti-EGFR therapy provides opportunities to identify emerging RAS mutant clones early during treatment. This minimally invasive approach provides better visualization of treatment responses and failures, enabling personalized therapy approaches for mCRC patients, with the goal of improving outcomes. The lead and senior authors of the study, Dr. Theodora Germetaki and Dr. Mark Saunders, Department of Medical/Clinical Oncology, The Christie Hospital, Manchester, UK conclude: "We showed that 20% of patients showed a change in their RAS mutational status during treatment. These results demonstrate there is an opportunity to more precisely understand an individual patient's tumor response using longitudinal plasma testing in order to establish new clinical decision points for the management of patients receiving EGFR inhibitor therapy." Ongoing studies are exploring the outcomes and cost-effectiveness of OncoBEAM RAS testing to guide the management of anti-EGFR treatment in mCRC patients.

Overall, this study shows the value of an ultrasensitive OncoBEAM liquid biopsy RAS test in overcoming sampling bias associated with tissue biopsy to enable rapid turn-around time of molecular test results for more timely initiation of first-line treatment and early detection of RAS mediated resistance in patients receiving anti-EGFR therapy.

The publication, titled "Blood-based *RAS* mutation testing: concordance with tissue-based *RAS* testing and mutational changes on progression," was published in *Future Oncology* July 27, 2020, by Theodora Germetaki, et al. https://www.futuremedicine.com/doi/10.2217/FON-2020-0523.

**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 OncoBEAMTM (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' OncoBEAMTM and SafeSEQ services are readily available to support clinical trials and research in oncology. In addition, OncoBEAMTM 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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