Sysmex Inostics GmbH

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Sysmex Inostics' OncoBEAMTM RAS CRC testing supports clinical outcome improvements for metastatic colorectal cancer patients rechallenged with anti-EGFR therapy

Baltimore, MD (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 RAS mutation status in circulating tumor DNA (ctDNA) of colorectal cancer (CRC) patients undergoing anti-EGFR antibody therapy (cetuximab or panitumumab) rechallenge using the OncoBEAM RAS CRC test in two different multicenter Japanese retrospective trials, JACCRO CC-08 and JACCRO CC-09.

OncoBEAM RAS CRC is a test that uses BEAMing technology, an enhanced digital PCR method optimized for high sensitivity blood-based mutation detection for metastatic colorectal cancer (mCRC) patients. In this study, investigators utilized the highly sensitive nature of OncoBEAM testing to explore the clinical value of monitoring changes in plasma RAS mutations in CRC patients during treatment with anti-EGFR antibody therapy.

Colorectal cancer continues to be one of the leading causes of cancer-related deaths globally. Treatment of mCRC patients with anti-EGFR monoclonal antibodies have demonstrated significant improvements in the survival of patients with wild-type RAS tumors. mCRC patients being considered for anti-EGFR therapy rechallenge could greatly benefit the overall patient survival by undergoing initial plasma testing to establish RAS mutation status at baseline, as well as performing subsequent tests to monitor RAS mutation dynamics during treatment. By receiving regular blood draws throughout the anti-EGFR rechallenge treatment, patients would benefit from periodic OncoBEAM RAS testing, which would in turn deliver valuable insights for clinicians in assessing therapy response.

The study published in JCO Precision Oncology by Sunakawa *et al*., demonstrated that RAS mutations were found in 38% of CRC patients after receiving the first course of anti-EGFR mAb therapy, but prior to rechallenge treatment. The disease control rate (DCR) was 33% in patients with RAS mutations in ctDNA, whereas it was 80% in patients without RAS mutation detected by OncoBEAM at baseline. The data also showed that patients with RAS mutations detected just before anti- EGFR mAb rechallenge had no survival benefit from rechallenge treatment. Moreover, post-progression survival time after rechallenge was worse in patients with RAS mutations than in patients without mutations at disease progression. The emergence of RAS mutations during rechallenge treatment at disease progression is therefore useful for predicting outcomes of anti- EGFR mAb therapy rechallenge.

"We found that the OncoBEAM RAS CRC assay was not only effective in monitoring the resistance to anti-EGFR therapy, but was also important in helping us determine the efficacy of the rechallenge treatment and therefore predict patients who would have favorable outcomes. Overall, our novel findings support the value of using the ultrasensitive OncoBEAM RAS liquid biopsy test in the clinical management of CRC patients receiving anti-EGFR mAb as rechallenge treatment. " stated Dr. Yu Sunakawa, MD, PhD, Department of Clinical Oncology, St Marianna University School of Medicine, Kawasaki, Japan.

Besides results of this publication, a new prospective observational trial "REMARRY (UMIN000036424)" has been initiated with over 100 patients recruited as of June 2020. This clinical trial, supported by SCRUM-Japan MONSTAR-SCREEN, will expand the evaluation of patient-specific dynamics in ctDNA RAS mutational status as a predictor of anti-EGFR mAb rechallenge efficacy. Overall, the aggregate results from these trials should strongly support the clinical utility of performing longitudinal plasma OncoBEAM RAS testing in monitoring tumor response during anti-EGFR antibody therapy.

The publication, titled "*RAS* Mutations in Circulating Tumor DNA and Clinical Outcomes of Rechallenge Treatment with Anti-EGFR Antibodies in Patients with Metastatic Colorectal Cancer," was published in *JCO Precision Oncology,* July 28, 2020, by Yu Sunakawa et al.: https://ascopubs.org/doi/full/10.1200/PO.20.00109.

The poster, titled "REMARRY and PURSUIT trials: Liquid biopsy-guided rechallenge of anti-EGFR monoclonal antibody for patients with RAS/BRAF V600E wild-type metastatic colorectal cancer" was presented at ESMO World Congress on Gastrointestinal Cancer 2020 by Hiromi Nakajima et al.:https://dx.doi.org/10.1016/j.annonc.2020.04.100.

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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