Sysmex Inostics GmbH

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University of Chicago Clinical Trial Utilizes Sysmex Inostics Highly Effective HPV-SEQ Test to Measure HPV-DNA from Blood of Neck and Throat Cancer Patients

Baltimore, MD (ots) -

Sysmex Inostics, a global leader in the liquid biopsy revolution for oncology, announces the use of their HPV-SEQ test in the prospective University of Chicago clinical trial,1 “Pilot Study of Chemotherapy for HPV-Associated Oropharyngeal Cancer.”

“The ability to reliably detect HPV-DNA in plasma at such low frequency shows HPV-SEQ could be a promising non-invasive biomarker test for effectively assessing treatment response, appropriately de-intensifying treatment using real-time dynamic HPV quantification, and monitoring HPV-positive OPC patients’ post-treatment,” said Dr. Nishant Agrawal, Professor of Surgery at the University of Chicago. “Therefore, the HPV-SEQ test has the potential to be an important tool for oncologists in treating patients with HPV-associated head and neck cancer,” he concluded.

Current standard therapy used to treat OPC patients is associated with acute and long-term toxicities from chemotherapy, radiation, and surgery.2 In the trial, Dr. Agrawal and team will dynamically assess the level of cfHPV-DNA in patients’ blood and use this information to de-intensify treatment which would improve therapeutic outcome while minimizing treatment associated toxicity.

Sysmex Inostics senior director of medical affairs, Fred Jones, noted, “The University of Chicago trial is a strong step forward in showing the clinical utility of HPV-SEQ test as a tool in treating patients with HPV-associated head and neck cancer. We look forward to the results of the trial.”

HPV associated OPC has increased dramatically over the last decade. In the United States HPV is thought to cause 70% of oropharyngeal cancers, back of the throat, including the base of the tongue and tonsils.3

Approximately 10 percent of men and 3.6 percent of women in the U.S. have HPV in their mouths and HPV infection is more commonly found with older age. While most people clear the infections on their own within a year or two, in some people HPV infection persists.4 Patients with HPV-driven disease respond better to treatment and demonstrate a more favorable prognosis, compared to patients with HPV negative head and neck cancer.

HPV-SEQ, Sysmex Inostics ultra-sensitive quantitative, CLIA-validated, blood test for the detection of cell-free HPV 16/18 DNA (cfHPV-DNA), will be used in the trial to monitor personalized treatment and de-escalation of HPV positive oropharyngeal cancer (OPC) patients. HPV-SEQ, which can detect as few as 5 HPV 16/18 molecules in a background of 20,000 wild-type molecules (0.025% allele frequency), empowers this ground-breaking trial. The protocol was published in the recent BMC Cancer paper,5 “Prospective study evaluating dynamic changes of cell-free HPV-DNA in locoregional viral-associated oropharyngeal cancer treated with induction chemotherapy and response-adaptive treatment.”

The trial is a follow-on to the poster6 presented at the 2021 ASCO Annual Meeting in which Dr. Agrawal described how HPV-SEQ exhibits robust quantitative detection of cfHPV-DNA across a broad dynamic range, thus enabling high-resolution monitoring for patients with HPV positive OPC.

HPV-SEQ is available as a testing service provided by the Sysmex Inostics CLIA lab in Baltimore. MD.

1. https://clinicaltrials.gov/ct2/show/record/NCT04572100

2. https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/chemotherapy-side-effects.html

3. https://ascopubs.org/doi/10.1200/EDBK_325319?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

4. https://www.hopkinsmedicine.org/kimmel_cancer_center/cancers_we_treat/head_neck/hpv/faqs.html

5. https://bmccancer.biomedcentral.com/articles/10.1186/s12885-021-09146-z

6. https://sysmex-inostics.com/new-asco-2021-poster-highlights-hpv-seq-tests-ultra-sensitive-detection-of-hpv-16-18-in-plasma/

About Sysmex Inostics

Sysmex Inostics, Inc., a US-based Sysmex Corporation subsidiary, empowers discoveries in oncology by providing investigators with ultra-sensitive, quantitative, and cost-effective CLIA-validated liquid biopsy services.

Since 2008, Sysmex Inostics has provided leading Pharma companies custom liquid biopsy assay services, first OncoBEAM™ and now Plasma-Safe-SeqS, to support real-time therapy selection and targeted-mutational monitoring during and after treatment throughout the clinical trial process.

Developed by experts at Johns Hopkins with the philosophy of “no molecule left behind,” Sysmex Inostics Plasma-Safe-SeqS has robust detection as low as 0.03% allele frequency (for input of 20,000 genomic equivalents) without sacrificing specificity. The venerable OncoBEAM™ digital PCR cell-free DNA (cfDNA) technology has been employed in hundreds of pivotal studies, publications, and numerous drug discoveries in oncology. Plasma-Safe-SeqS NGS technology, introduced in 2019, is currently being used in various clinical studies.

In July 2021, Sysmex Corporation announced a global strategic alliance with QIAGEN to expedite clinical trial timelines and CDx development by uniting QIAGEN’s commercial and regulatory expertise with the liquid biopsy scientific rigor and knowledge of Sysmex Inostics.

Sysmex Inostics offersPlasma-Safe-SeqS services in its CLIA-certified laboratory in Baltimore, Maryland.

For more information, refer to www.sysmex-inostics.com or email info@sysmex-inostics.com.

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