Sysmex Inostics GmbH

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Sysmex Inostics Presents Data at the American Society of Hematology Annual Meeting Demonstrating Exquisite Sensitivity of SafeSEQ NGS Technology for Detection of Measurable Residual Disease in Acute Myeloid Leukemia

Baltimore, MD (ots) -

Sysmex Inostics, Inc., a global leader and pioneer in blood-based, high-sensitivity molecular testing for oncology, is presenting the poster "Ultrasensitive Measurable Residual Disease (MRD) Detection in Acute Myeloid Leukemia (AML) Using a Targeted Next Generation Sequencing (NGS) Panel" at the 62nd Annual American Society of Hematology (ASH) Virtual Meeting on Saturday, December 5th. Viewing time is between 7:00 AM and 3:30 PM (Pacific Standard Time)."

AML is one of the deadliest blood cancers that takes over 10,000 lives in the U.S. each year. If cancer relapses after treatment, the prognosis is typically poor. Therefore, after initial treatment, patients are tested for MRD as a prognostic indicator of therapeutic effectiveness and relapse risk.

Groundbreaking FDA-approved AML therapeutics, such as ivosidenib, have been developed to target *IDH1* mutations, which are present in about 5-10% of AML patients and can increase risk of relapse. Both newly diagnosed and relapsed/refractory AML patients with mutant *IDH1* can benefit from *IDH*-directed therapy. In several clinical trials, the Sysmex Inostics OncoBEAM(TM) enhanced digital PCR technology has been used to monitor the levels of *IDH* mutations present in AML patients receiving targeted therapies. OncoBEAM(TM) technology is widely considered a gold standard for high sensitivity molecular testing and continues to be one of the most sensitive digital PCR approaches, capable of detecting mutations reliably at 0.02% mutant allele frequency (MAF).

Current NGS pan-heme panels lack sufficient sensitivity for reliable detection of molecular MRD, as their limits of detection are between 1-5% mutant allele frequency. Sysmex Safe-SeqS technology (SafeSEQ) dramatically expands the breadth of mutation detection for targets with established and emerging clinical validity for AML MRD while delivering comparable sensitivity to OncoBEAM. This highly sensitive, error-corrected NGS-based method can reliably detect molecular MRD present at levels as low as five mutant molecules, which is similar to the limit of detection observed across other SafeSEQ platform configurations and corresponds to 0.025% MAF for 20,000 genomic copies (66 ng of DNA) input.

In addition to demonstrating robust analytical performance, 100% overall agreement was observed between SafeSEQ and OncoBEAM for the detection of *IDH1* mutations in clinical samples from AML patients. Furthermore, in almost all (94%) patients tested, at least one additional mutation outside of *IDH1* was detected by the SafeSEQ AML MRD assay, which is consistent with previous observations that *IDH* mutations can co-occur with drivers in other genes such as *NPM1* and may provide additive value for MRD detection.

"In order to deliver a powerful clinical tool for molecular MRD detection for AML patients, we developed the SafeSEQ AML MRD test to provide additional information across the most highly relevant genomic regions, with sensitivity comparable to the focused OncoBEAM method," said Matt Ryder, Director of Translational Science at Sysmex Inostics. "By offering reliable detection of molecular MRD with 50 to 100 times greater sensitivity versus 'pan-heme' NGS tests, the Plasma-SeqSensei AML MRD test will help accelerate clinical development of novel therapeutics and, ultimately, provide oncologists with more reliable information on which to base important decisions for their AML patients."

Poster number 1078, "Ultrasensitive Measurable Residual Disease (MRD) Detection in Acute Myeloid Leukemia (AML) Using a Targeted Next Generation Sequencing (NGS) Panel" presented by Hillary Sloane, Associate Director of Medical & Scientific Affairs at Sysmex Inostics, will be available Saturday, December 5th from 7:00 AM to 3:30 PM (Pacific Standard Time) at the 62nd ASH Annual Meeting during the Acute Myeloid Leukemia: Biology, Cytogenetics, and Molecular Markers in Diagnosis and Prognosis poster session number 617.

About Sysmex Inostics

Sysmex Inostics, a Sysmex Corporation subsidiary, empowers discoveries in oncology by providing investigators cost-effective and ultra-sensitive quantitative liquid biopsy solutions, OncoBEAM(TM) (digital PCR), and SafeSEQ (NGS).

Developed by experts at Johns Hopkins with the philosophy of "no molecule left behind," these technologies are optimized to ensure the detection of low-frequency mutant molecules (<0.05% MAF) with a high degree of specificity. Focused and flexible genomic coverage allows for superior sensitivity and reduced costs.

As pioneers in blood-based cell-free tumor DNA (ctDNA) mutation detection, Sysmex Inostics has provided custom assays and CLIA-certified lab services to leading BioPharma companies over the last ten years to help develop therapeutics to extend lives and companion diagnostics to monitor progression, identify targetable resistance alterations, and detect minimal residual disease (MRD).

Sysmex Inostics' OncoBEAM(TM) and SafeSEQ services are readily available and customizable to support clinical trials and research in oncology. OncoBEAM(TM) tests are available through a CLIA-certified laboratory for routine clinical analysis and distributed kit products in the E.U.

Sysmex Inostics' European headquarters for research & development GCP laboratory testing are located in Hamburg, Germany; Sysmex Inostics' U.S. headquarters and 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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