Sysmex Inostics GmbH

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New Ultra-Sensitive Leukemia Blood Test Delivered by Sysmex Inostics

Baltimore, MD (ots) -

-- New Tool for Detection of Minimal Residual Disease in Acute Myeloid Leukemia to Better Help in Fight Against Cancer --

Sysmex Inostics has developed a new CLIA-validated liquid biopsy test for the detection of Minimal Residual Disease (MRD) in Acute Myeloid Leukemia (AML). A global leader and pioneer in blood-based, ultra-sensitive molecular testing for oncology, the company's new test uses a targeted Next Generation Sequencing (NGS) panel.

"The new test, AML-MRD-SEQ, offers clinical trial sponsors, and eventually physicians and patients, an early signal for the presence of cancer cells following initial therapy. This new liquid biopsy solution is a major step in developing treatment strategies to support the fight against a devastating disease," said Shinichi Sato, CEO of Sysmex Inostics, Inc.

This new test, AML-MRD-SEQ, adds to the portfolio of ultra-sensitive Plasma-Safe-SeqS technology NGS tests available through Sysmex Inostics' CLIA lab services in Baltimore, Maryland.

Previous generations of AML MRD tests were only able to detect a limited number of mutations that have an established therapeutic indication.AML-MRD-SEQ offers a more expansive panel covering 68 regions across 20 genes, including established MRD markers such as *NPM1*, and demonstrating significant potential for use as an investigational tool for other markers with prognostic values that are not yet well-established. The new highly sensitive AML-MRD-SEQ test with broader genomic coverage offers the opportunity for early intervention and clinical trial enrollment.

"Sysmex Inostics' mission is to develop new innovative tools and expand partnerships with top-tier global biopharmaceutical companies to further advance drug development and treatments for the benefit of oncology patients worldwide," Sato concluded.

AML-MRD-SEQ offers reliable detection of molecular MRD with 50 to 100 times greater sensitivity versus other currently available NGS pan-heme tests.1,2 Such ultra-sensitive detection of low-level mutant molecules allows clinical trial sponsors to execute on clinical development timelines more efficiently.

AML is one of the deadliest blood cancers, resulting in more than 10,000 lives lost in the U.S. each year.3 Because AML relapses usually result in a poor prognosis, it is necessary to test patients for MRD after initial treatment as a prognostic indicator of therapeutic effectiveness and relapse risk. Applying Sysmex Inostics' ultra-sensitive liquid biopsy NGS technology, Plasma-Safe-SeqS, to the detection of gene mutations associated with AML MRD enables accelerated clinical development timelines, cost savings, and improved outcomes throughout the clinical trial process.

A recent market research report states that the liquid biopsy market is estimated to achieve an annual growth rate of more than 35% over the next few years, reaching $4 billion by 2024.4 The analysis notes that an increasing focus on personalized medicine for cancer care is driving the tremendous growth.

About Sysmex Inostics

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

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 circulating 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 monitor progression, identify targetable resistance alterations, and detect MRD throughout the clinical trial process.

In July 2021, Sysmex Corporation announced a global strategic alliance with QIAGEN to provide custom cancer companion diagnostics (CDx) utilizing Plasma-Safe-SeqS technology. The alliance is intended to promote early clinical implementation of Sysmex Inostic's technology to expedite clinical trial timelines for pharmaceutical companies that develop molecularly targeted drugs for cancer.

Sysmex Inostics offers a portfolio of highly sensitive NGS panels through its CLIA-certified laboratory in Baltimore, Maryland.

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

References:

1. https://ots.de/lSbzVr

2. https://ots.de/UiG3mw

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