Sysmex Inostics GmbH

02.08.2019 – 08:00 Uhr

Sysmex obtains Japanese manufacturing and marketing approval for the first blood-based RAS mutation testing for colorectal cancer

Japan (ots) -

Sysmex Corporation has obtained Japanese manufacturing and marketing approval for the OncoBEAM(TM) RAS CRC Kit, used for blood-based circulating tumor DNA (ctDNA) molecular testing of mutations in the RAS gene for advanced colorectal cancer patients. With clinically-validated high sensitivity and specificity for ctDNA molecular characterization and an extensive publication history, the approval of the OncoBEAM RAS CRC Kit marks the first approval of a liquid biopsy test in Japan and will provide CRC patients with a viable alternative to tissue testing. Availability of the OncoBEAM RAS CRC kit in Japan will reduce the need for invasive tissue biopsy and expedite the delivery of important molecular information required for the accurate prescription of therapy for patients suffering from colorectal cancer.

Jointly developed between Sysmex Corporation subsidiary Sysmex Inostics and Merck KGaA Darmstadt, Germany, the OncoBEAM RAS CRC Kit received CE Marking in 2016 (CE = European Conformity, certification mark in European Economic Area). For the approval in Japan, eight facilities were involved in a multi-center evaluation, including the National Cancer Center Hospital East (Kashiwa City, Japan). Across the world, numerous peer-reviewed publications have demonstrated the robust clinical performance of the OncoBEAM RAS CRC Kit, and its availability in Japan is anticipated to greatly improve the management of patients with colorectal cancer.

By providing timely information from ctDNA in the bloodstream of colorectal cancer patients, OncoBEAM RAS testing can be used by physicians to determine whether to use molecularly targeted anti-EGFR drugs (e.g. Cetuximab) in the course of treatment. Sysmex Corporation anticipates launching an OncoBEAM RAS CRC Assay Service to further widen adoption of this important capability for precision medicine for Japanese patients, in addition to applying for national insurance coverage.

The manufacturing and marketing approval in Japan was obtained 19 July 2019 from Japan's Ministry of Health, Labour and Welfare (MHLH), approval number 30100EZX00010000.

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 OncoBEAM(TM) (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' OncoBEAM(TM) and SafeSEQ services are readily available to support clinical trials and research in oncology. In addition, OncoBEAM(TM) tests are available through a CLIA certified laboratory for routine clinical analysis as well as distributed kit products in the EU and Asia Pacific.

Sysmex Inostics' headquarters and GCP Service Laboratory are located in Hamburg Germany; Sysmex Inostics' 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.

Contact:

Sysmex Inostics
Press Release
Phone: +49-(0)-40-3259070
Mail: info@sysmex-Inostics.com