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Sysmex gets Japanese manufacturing and marketing approval

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Sysmex Corporation has obtained Japanese manufacturing and marketing approval for the OncoBEAM™ 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.