Illumina Comprehensive Genomic Profiling Test for Cancer Receives Regulatory Approval in Japan

TruSight™ Oncology Comprehensive for cancer genomic profiling is expected to expand access to precision oncology options for patients in Japan

JAPAN, Tokyo May 27, 2025 /Business Wire/ -- Illumina, Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, announced today that it has received approval from the Ministry of Health, Labour and Welfare (MHLW) for TruSight™ Oncology (TSO) Comprehensive for Class III/IV Medical Device (Specially Controlled Medical Device) in Japan. As genomic insights continue to drive breakthroughs in cancer treatment, the test is designed to make precision oncology more accessible to oncologists and patients.

This single test includes analysis of DNA and RNA variants and interrogates over 500 genes to profile a patient's solid tumor, helping to increase the likelihood of identifying clinically actionable biomarkers that enable targeted therapy selection or clinical trial enrolment. This CGP test is powered by a streamlined, automated sample-to-report workflow, will enable clinicians in Japan to accelerate access to personalized medicine decisions with greater efficiency and precision.

"Genomics helps bring precision medicine to life as it enables clinicians to match available treatments to a patient's genetic tumor profile, which has the potential to improve cancer treatment and quality of life for patients," said Catherine Ohura, General Manager at Illumina Japan. "We look forward to bringing this genomic profiling test to Japan, improving access to precision medicine solutions for cancer patients."

TruSight Oncology Comprehensive is the first US FDA-approved, distributable comprehensive genomic profiling IVD kit with pan-cancer companion diagnostic claims in the US.
Its separate CE-marked (Conformité Européenne) version of TSO Comprehensive was first launched in Europe in 2022.

"Cancer is a disease of the genome, and we know that genomic insights from next-generation sequencing can lead to better oncology outcomes. We are committed to working with government, patients, and the medical community to bring attention to the need for ongoing investment in education and infrastructure needed in Japan to integrate genomics as a standard part of care in the fight against cancer," Ohura said.

Illumina's oncology portfolio adapts to global customer needs with versatile, scalable solutions—from low- to high-throughput instruments. Through pharmaceutical partnerships, the company is developing an expanding pipeline of companion diagnostics (CDx). By collaborating with industry leaders, Illumina advances its oncology portfolio to drive progress in cancer diagnostics and precision medicine.

Illumina's clinical oncology portfolio will be featured at the ASCO Annual Meeting in Chicago May 30-June 3.

About TSO Comprehensive

TSO Comprehensive is the first FDA-approved distributable comprehensive genomic profiling IVD kit with pan-cancer CDx claims in the US. Comprehensive genomic profiling is a next-generation sequencing approach that uses a single assay to assess hundreds of genes—including relevant cancer biomarkers, as established in guidelines and clinical trials—for therapy guidance. TSO Comprehensive interrogates over 500 genes to profile a patient's solid tumor, helping to increase the likelihood that an immuno-oncology biomarker or clinically actionable biomarkers will be identified. This can open up options such as targeted therapy or clinical trial enrollment. A separate CE-marked version of TSO Comprehensive is also available in Europe.

Learn more about TruSight Oncology Comprehensive

Use of forward-looking statements

This release may contain forward-looking statements that involve risks and uncertainties. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) our ability to manufacture robust instrumentation and consumables; (ii) challenges inherent in developing, manufacturing, and launching new products and services, including expanding or modifying manufacturing operations and reliance on third-party suppliers for critical components; (iii) our ability to obtain regulatory approval for our products from government agencies; (iv) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current quarter.

About Illumina

Illumina is improving human health by unlocking the power of the genome. Our focus on innovation has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on X (Twitter), Facebook, LinkedIn, Instagram, TikTok, and YouTube.

For Media Inquiries:

Press Office
Illumina_JP@webershandwick.com

Sam Shen
Director, Corporate Communication AMEA & Greater China
Sam.shen@illumina.com
+86 1367 1791 029