MediaRoom

Oncomine Dx Target Test Receives MHLW Approval as a Companion Diagnostic for Eli Lilly's RET-Inhibitor in Non-Small Cell Lung Cancer in Japan

CARLSBAD, Calif., Sept. 10, 2021 /PRNewswire/ -- Thermo Fisher Scientific today announced the Japan Ministry of Health, Labour and Welfare (MHLW), Japan's regulatory agency, has granted approval for the Oncomine Dx Target Test as a next-generation sequencing (NGS)-based companion diagnostic (CDx) for patients with RET-fusion positive non-small-cell lung cancer (NSCLC) who may be treated with Eli Lilly and Company's selpercatinib (formerly known as LOXO-292). The MHLW granted orphan drug designation for selpercatinib, a tyrosine kinase inhibitor that selectively binds to the RET receptor, in 2020.

"This approval will help patients suffering from non-small cell lung cancers whose tumors are positive for fusions in the RET receptor, providing access to new, potentially more effective treatments," said Hiroo Murota, vice president and general manager, Thermo Fisher Scientific Japan. "We will continue to advance precision medicine by expanding our companion diagnostic tests that identify biomarkers associated with targeted therapies."

Thermo Fisher currently offers the only globally-distributable NGS companion diagnostic solution approved and reimbursed by government and commercial insurers in more than 15 countries, including the U.S., multiple European nations, Japan, South Korea and the Middle East, covering more than 550 million lives globally.

Thermo Fisher's Oncomine Dx Target Test now has approvals in Japan for five biomarkers with a total of ten associated targeted therapies for NSCLC patients. The CDx markers and therapies include:

- *BRAF* V600E mutation – dabrafenib in combination with trametinib
- *EGFR* mutations – afatinib, gefitinib, erlotinib, osimertinib
- *ALK* fusions – alectinib, crizotinib
- *ROS1* fusions– crizotinib, entrectinib
- *RET* fusions – selpercatinib

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