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ASIA EDITION

Thermo Fisher’s oncomine test receives expanded approval

01 March 2019 | News

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Thermo Fisher Scientific recently announced that the Ministry of Health, Labour and Welfare (MHLW), Japan's regulatory agency, has granted expanded approval to the Oncomine Dx Target Test CDx System.

The next-generation sequencing (NGS)-based multiplex companion diagnostic (CDx) test simultaneously evaluates patient tumor samples for biomarkers associated with targeted therapies for non-small cell lung cancer (NSCLC).

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Following the April 2018 approval of the test in Japan as a CDx to identify NSCLC patients who may benefit from therapies targeting the BRAF (V600E) mutation, the MHLW has expanded its approval to include three additional biomarkers with a total of eight associated targeted therapies for NSCLC patients.

The CDx markers and therapies include EGFR exon 19 deletion mutation and EGFR exon 21 L858R mutation – afatinib, gefitinib, erlotinib, osimertinib; ALK fusion gene – alectinib, crizotinib; ROS 1 fusion gene – crizotinib; BRAF V600E mutation – Combined therapy of dabrafenib and trametinib (approved April 2018).

Oncomine Dx Target Test received national healthcare insurance reimbursement coverage in December 2018 for patients tested for the BRAF (V600E) gene mutation in Japan. Thermo Fisher anticipates the expanded markers on the test will also receive reimbursement coverage in the coming months.