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USFDA approves Thermo Fisher's Oncomine Dx Target Test for lung cancer detection

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The US Food and Drug Administration (FDA) has granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target Test as a companion diagnostic (CDx) to identify patients whose tumours have a HER2 (ERBB2) activating mutations (SNVs & Exon 20 Insertion) in non-small cell lung cancer (NSCLC) who may be candidates for ENHERTU (fam-trastuzumab deruxtecan-nxki).

ENHERTU is a specifically engineered HER2-directed antibody-drug conjugate (ADC) being jointly developed and commercialised by Japanese firm Daiichi Sankyo and AstraZeneca.

The FDA approved ENHERTU on August 11 for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumours have a HER2 (ERBB2) activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy. The approval follows a Priority Review, granted by the US FDA in April 2022.

The Oncomine Dx Target Test is currently the only distributed next-generation sequencing (NGS) CDx that has received regulatory approval and is available in 17 countries for 15 targeted therapies, covering more than 550 million lives globally. It is designed to simultaneously evaluate 23 genes associated with NSCLC. The test received its first approval by the FDA as a CDx in 2017. In the US alone, it is approved for seven targeted therapies for NSCLC and one for cholangiocarcinoma.