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Thermo Fisher receives US FDA approval for NGS-based Oncomine Dx Target Test as companion diagnostic

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NGS-based companion diagnostic for new non-small cell lung cancer treatment



Thermo Fisher Scientific, the world leader in serving science, has received approval from the US Food and Drug Administration (FDA) for its Oncomine Dx Target Test as a companion diagnostic (CDx) to identify patients who may be candidates for HERNEXEOS® (zongertinib tablets), a tyrosine kinase inhibitor (TKI), developed by Boehringer Ingelheim.

The test allows clinicians and pathologists to assess if non-small cell lung cancer (NSCLC) tumours harbor human epidermal growth factor receptor 2 (HER2/ERBB2) tyrosine kinase domain (TKD) activating mutations.

The US FDA approved HERNEXEOS on August 8, 2025 as the first and only orally administered targeted therapy for adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumours have HER2 (*ERBB2*) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy. This indication was approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Lung cancer is the second most common cancer in both men and women in the United States, with NSCLC accounting for about 85–90% of all lung cancer cases. Among those diagnosed with NSCLC, approximately 2 to 4 percent of patients present with a HER2 mutation.