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Thermo Fisher, Daiichi Sankyo to co-develop CDx for NSCLC

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The Global Companion Diagnostic agreement centers on identifying HER2 gene mutations using Oncomine Dx Target Test

Thermo Fisher Scientific and Daiichi Sankyo have expanded their partnership by signing a new agreement to co-develop a companion diagnostic (CDx) that will utilize Thermo Fisher's next-generation sequencing (NGS)-based Oncomine Dx Target Test. The CDx will be designed to identify non-small cell lung cancer (NSCLC) patients with human epidermal growth factor receptor 2 (HER2) mutations who may be eligible for Enhertu, a HER2 directed antibody-drug conjugate (ADC), which is currently in global phase 2 development for HER2 mutated or HER2 overexpressing NSCLC.

Enhertu has demonstrated a strong response rate in patients with HER2 positive metastatic breast cancer and preliminary results show a similar response in patients with metastatic NSCLC with HER2 mutations. HER2 mutations have long been implicated in breast cancers, but they are considered a rare event in NSCLC. Recent studies have found that HER2 mutations are the key drivers in about 1-3 percent of NSCLC cases.

Under the terms of the agreement, Thermo Fisher will retain rights to commercialize the test globally and will seek approval from regulatory agencies. The announcement follows a 2018 agreement between the companies to expand the clinical utility of the test in support of clinical trials and drug development programs at Daiichi Sankyo.

The Oncomine Dx Target Test is the first targeted NGS *in vitro* diagnostic test approved by the U.S. Food and Drug Administration (FDA) for NSCLC. It is designed to evaluate multiple biomarkers associated with cancer and identify patients who are eligible for multiple FDA-approved targeted therapies using a single sample with results available in days.

“Our latest partnership with Daiichi Sankyo is focused on helping to solve an unmet medical need for a growing number of patients with HER2-mutated non-small cell lung cancer,” said Garret Hampton, president of clinical next-generation sequencing and oncology at Thermo Fisher Scientific. “This agreement underscores our continued commitment to working with global pharmaceutical partners to efficiently identify more patients who may benefit from the latest targeted therapies in their drug pipelines.”

U.S. FDA-Approved Indication for ENHERTU

ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

This indication is approved under accelerated approval based on tumor 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.