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Thermo Fisher signs pact with Lilly Oncology

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Strategic agreement utilizes FDA-approved next-generation sequencing Oncomine Dx Target Test to identify RET-altered non-small cell lung cancer and thyroid cancer patients who may be suitable for LOXO-292, Lilly's RET inhibitor



Thermo Fisher Scientific has announced an agreement with Eli Lilly and Company for development of a companion diagnostic that will use the U.S Food and Drug Administration-approved, next-generation sequencing-based Oncomine Dx Target Test to identify certain non-small cell lung cancer (NSCLC) and thyroid cancer patients who may be treated with Lilly's investigational therapy, LOXO-292. Specifically, the test would be used with patients whose tumors harbor a rearranged during transfection (RET) alteration. *RET* variants are found in about two percent of NSCLC, about 60 percent of medullary thyroid cancer (MTC) and up to approximately 20 percent of other thyroid cancers.

LOXO-292 is a highly selective and potent oral RET inhibitor being studied by Lilly in a Phase 1/2 clinical trial for the treatment of advanced cancers that harbor activating alterations of the RET kinase. Changes in the RET kinase, including fusions and mutations, can cause uncontrolled cell growth leading to tumor development. Cancers driven by such alterations are mostly dependent on this singularly activated pathway, making them highly susceptible to small molecule inhibitors.

Under the terms of the agreement, Thermo Fisher will retain the rights to commercialize the test in all markets, including the United States, Europe and Japan. Once validation is complete, Thermo Fisher will submit a supplemental premarket approval (sPMA) application to the U.S. Food and Drug Administration (FDA) to broaden the clinical claims of its Oncomine Dx Target Test.

The NGS test, which received FDA approval in 2017, simultaneously screens tumor samples for multiple gene variants associated with NSCLC, a subset of which are utilized to identify patients who may be eligible for several approved targeted therapies. It is covered in the United States by the Centers for Medicare & Medicaid Services and a majority of the largest commercial U.S. health plans. Oncomine Dx Target Test is also approved for reimbursement by the Japan Ministry of Health, Labor and Welfare (MHLW).