MediaRoom

Thermo Fisher Scientific Signs Oncology Companion Diagnostic Development Agreement with Blueprint Medicines

Agreement to expand Oncomine Dx Target Test with RET fusion markers to treat non-small cell lung cancer patients

CARLSBAD, Calif., Oct. 31, 2017 /PRNewswire/ -- As part of its ongoing commitment to increase the utility of next-generation sequencing (NGS) in the clinic, Thermo Fisher Scientific announced today it has expanded the development of its Oncomine Dx Target Test by entering into an agreement with Blueprint Medicines Corporation to develop and commercialize the Oncomine Dx Target Test as a companion diagnostic (CDx) for BLU-667 to identify RET fusions in people with non-small cell lung cancer (NSCLC).

Taken orally, BLU-667 is a potent and selective inhibitor of the kinase RET, including RET fusions and mutations, currently being evaluated by Blueprint Medicines in a Phase 1 clinical trial for the treatment of patients with RET-driven NSCLC, thyroid cancer and other advanced solid tumors (NCT03037385). The CDx will complement efforts to drive enrollment to the trial. Once validation is complete, Thermo Fisher will submit a supplemental premarket approval application to the U.S. Food and Drug Administration (FDA) to expand the clinical claims for its Oncomine Dx Target Test.

Under the terms of the agreement, Thermo Fisher will also retain the rights to commercialize the test globally and will lead all necessary filings to seek clearance from regional regulatory agencies for the test. Expansion of the CDx is part of a strategic plan to develop one test for multiple therapies. Use of an approved multi-gene CDx to simultaneously screen patients for targeted therapies is a shift away from the conventional testing method of running several, single-biomarker analyses in sequence to identify tumor profiles.

Studies have shown that RET fusions and mutations are present in multiple cancers. In NSCLC, which accounts for 85 percent of all lung cancers in the United States,[1] RET fusions are believed to be key disease drivers in about 1-2 percent of patients. There are more than 220,000 new cases of lung cancer each year in the U.S., and the disease leads to more deaths than colon, breast and prostate cancer combined, according to the American Cancer Society.

The agreement with Blueprint Medicines marks the second CDx development program Thermo Fisher has signed this year to expand the Oncomine Dx Target Test, which received FDA approval in June and its first positive coverage decision by Regence Blue Cross Blue Shield this month. In May, the company announced a similar agreement with Agios Pharmaceuticals to expand the test's indication to include IDH1 mutations in cholangiocarcinoma, a rare form of cancer that affects the human bile duct system with a high unmet medical need.

"We are pleased to work with Blueprint Medicines and leverage the expandability of the FDA-approved Oncomine Dx Target Test to offer it as a companion diagnostic for BLU-667," said Joydeep Goswami, president of Clinical Next-Generation Sequencing and Oncology at Thermo Fisher Scientific. "It also helps us accelerate delivery on our commitment to bring NGS to mainstream clinical practice so that patients can start benefiting from targeted therapies more quickly."

1.Non–Small Cell Lung Cancer: Epidemiology, Risk Factors, Treatment, and Survivorship; Julian R. Molina, MD, PhD, Ping Yang, MD, PhD, Stephen D. Cassivi, MD, Steven E. Schild, MD, and Alex A. Adjei, MD, PhD

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