MediaRoom

FDA Approves NGS-Based Companion Diagnostic for Previously Treated IDH1-Mutated Cholangiocarcinoma

CDx approval expands clinical utility of Oncomine Dx Target Test to identify candidates for TIBSOVO

CARLSBAD, Calif., Aug. 25, 2021 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has granted pre-market approval to Thermo Fisher Scientific's Oncomine Dx Target Test as a companion diagnostic (CDx) to identify patients with isocitrate dehydrogenase-1 (IDH1) mutated cholangiocarcinoma (CCA) who may be candidates for Servier Pharmaceuticals' TIBSOVO® (ivosidenib tablets). TIBSOVO is an IDH1 inhibitor that is approved for the treatment of adult patients with previously treated, locally advanced or metastatic CCA with an IDH1 mutation as detected by an FDA-approved test.

CCA is a rare, aggressive cancer of the bile ducts within and outside of the liver. IDH1 mutations occur in up to 20 percent of CCA cases in the Unites States and are not associated with prognosis.[1] Prior to the approval of TIBSOVO on August 25, 2021, there were no approved targeted therapies for IDH1-mutated cholangiocarcinoma and limited chemotherapy options are available in the advanced setting.[2]

TIBSOVO is also approved in the U.S. as monotherapy for the treatment of adults with IDH1-mutated relapsed or refractory acute myeloid leukemia (AML) and for adults with newly diagnosed IDH1-mutated AML who are ≥75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy. The approval of TIBSOVO in previously treated IDH1-mutated CCA is supported by data from the ClarIDHy study, the first and only randomized Phase 3 trial for previously treated IDH1-mutated CCA.

"Prior to today, patients with IDH1-mutated cholangiocarcinoma did not have an approved targeted therapy treatment option," said Susan Pandya, M.D., vice president, clinical development, head of cancer metabolism global development, Servier Pharmaceuticals. "The FDA approval of TIBSOVO (ivosidenib tablets) for patients with previously treated IDH1-mutated cholangiocarcinoma is a major milestone for the cholangiocarcinoma community. I'd like to acknowledge and thank all the patients, their families and the investigators and research teams who took part in the ClarIDHy study, as well as Thermo Fisher Scientific for their partnership."

The Oncomine Dx Target Test is a next-generation sequencing (NGS) based test that delivers robust and reproducible results in the IDH1 gene clinically associated with CCA. The FDA first approved the test as a CDx in 2017, and it is now approved for four targeted therapies for non-small cell lung cancer (NSCLC) and one targeted therapy for CCA in the U.S. The test is currently approved and reimbursed by government and commercial insurers in over 15 countries, including U.S., Europe, Japan, South Korea and the Middle East, covering more than 550 million lives globally.

"With the FDA approval of Oncomine Dx Target Test as a companion diagnostic for TIBSOVO, healthcare providers across the U.S. can now match patients with this critically needed therapy," said Garret Hampton, president of clinical next-generation sequencing and oncology at Thermo Fisher Scientific. "Advances in genetic profiling through NGS have enabled identification of an increasing number of cancer-driving genomic variations, opening the door for the development of more targeted treatment options. By continuing to work with our pharmaceutical partners to co-develop diagnostics for these life-changing therapies and expanding the clinical utility of our tests, we hope to help more cancer patients around the world receive more targeted and effective treatment."

Thermo Fisher also has an agreement with Servier to develop and commercialize a CDx leveraging the Oncomine Precision Assay* to identify low-grade glioma (LGG) patients with isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2) mutations who may be eligible for vorasidenib (AG-881). The Oncomine Precision Assay runs on the Ion Torrent Genexus* System, the first fully integrated NGS platform featuring an automated specimen-to-report workflow that delivers results economically in a single day.

*This assay and instrument are currently For Research Use Only. Not for use in diagnostic procedures.

About Thermo Fisher Scientific
Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue exceeding $30 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them. Our global team of more than 80,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services and Patheon. For more information, please visit www.thermofisher.com.

[1] Boscoe, A., Rolland, C., & Kelley, R. (2019). Frequency and prognostic significance of isocitrate dehydrogenase 1 mutations in cholangiocarcinoma: a systematic literature review. *Journal Of Gastrointestinal Oncology, 10*(4), 751-765. Available at: https://jgo.amegroups.com/article/view/28868

[2] American Cancer Society. Key Statistics for Bile Duct Cancer. Available at: https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html.

Media Contact Information:
Mauricio Minotta
Phone: 760-805-5266
Email: mauricio.minotta@thermofisher.com

Jen Heady
Phone: 617-275-6547
Email: jheady@greenough.biz

SOURCE Thermo Fisher Scientific
