FDA approves Oncomine Dx Target test as a CDx for Tibsovo

Aug. 27, 2021—The FDA has granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target test as a companion diagnostic to identify patients with isocitrate dehydrogenase-1 mutated cholangiocarcinoma who may be candidates for 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.

Tibsovo (Servier Pharmaceuticals) is also approved in the U.S. as monotherapy for the treatment of adults with IDH1-mutated relapsed or refractory acute myeloid leukemia and for adults with newly diagnosed IDH1-mutated AML who are 75 years old or older or who have comorbidities that preclude the use of intensive induction chemotherapy.

The Oncomine Dx Target test is a next-generation-sequencing–based test that delivers robust and reproducible results in the IDH1 gene clinically associated with CCA. The test is approved and reimbursed by government and commercial insurers in more than 15 countries.