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Thermo Fisher's Oncomine Dx Test Approved for Identifying Patients for VORANIGOÃ?Â® in IDH-Mutant Glioma

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FDA approval enables Thermo Fisher's diagnostic test to guide treatment for patients with Grade 2 IDH-mutant glioma, the first targeted therapy available for this aggressive brain cancer.



Oncomine Dx Target Test to Identify Patients Eligible for Servier's VORANIGO® (vorasidenib) tablet, the only FDA-approved treatment for Grade 2 IDH-mutant glioma

Thermo Fisher Scientific, the world leader in serving science, has received approval from the U.S. Food and Drug Administration (FDA) for its Ion Torrent™ Oncomine™ Dx Target Test as a companion diagnostic (CDx) to identify patients eligible for treatment with Servier Pharmaceuticals, LLC's VORANIGO® (vorasidenib) tablets. VORANIGO is an isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection or gross total resection. As the first targeted therapy for Grade 2 IDH-mutant glioma, VORANIGO provides a new care path for patients with extremely limited treatment options.

Gliomas are the most common malignant primary brain tumor in adults, representing approximately 81% of primary malignant brain tumors. Of those, approximately 20% harbor an IDH mutation and testing for these mutations is essential for accurate treatment decisions. Further, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology recommend IDH mutation testing in all patients with a glioma, noting its impact on diagnosis and prognosis of gliomas. IDH mutation status has been a key factor in the NCCN treatment guidelines for years. With the FDA approval of VORANIGO, determining the IDH mutation status of patients with glioma will be even more critical.

"VORANIGO is the first and only targeted therapy for patients living with grade 2 IDH mutant glioma, a relentless and incurable type of brain cancer that hasn't seen treatment advances in nearly 25 years," said David K. Lee, CEO of Servier Pharmaceuticals. "As more targeted therapies become available to patients, identifying key driver mutations is essential to help the right patients find the right treatment, at the right time."

In addition to the approval for IDH-mutant diffuse glioma, the Oncomine Dx Target Test, has also previously received approvals for indications in non-small cell lung cancer (NSCLC), cholangiocarcinoma (CCA), medullary thyroid cancer (MTC) and thyroid cancer (TC). As a distributable companion diagnostic, the test simultaneously delivers biomarker results

for multiple targeted therapies from one sample, helping quickly match patients with the right targeted therapies.

“As the healthcare system works to realize the impact of precision medicine, patients must have access to the proper testing that helps unlock targeted treatment options based on their unique genomic profiles. This access is the driving motivation behind the extensive work we do with pharma partners to help connect the right patients to new therapies as soon as they are approved,” said Kathy Davy, president, clinical next-generation sequencing at Thermo Fisher Scientific. “The work we do every day reflects our Mission, and combining our CDx technology with Servier’s breakthrough therapy will help dramatically impact care for patients with aggressive brain tumors.”

Today’s approval expands clinical indications for the Oncomine Dx Target Test, which is currently approved and reimbursed by government and commercial insurers in 19 countries, including the U.S., Japan, South Korea and countries across Europe and the Middle East, covering more than 550 million lives globally.

Following this approval, the two organizations will continue to collaborate on an additional companion diagnostics with the Ion Torrent™ Oncomine Dx Express Test.* Available on the Ion Torrent Genexus™ Dx System*, the Oncomine Dx Express Test can return results in as little as a single day, dramatically accelerating the pace with which patients can be matched with optimal treatments based on their genomic results.

*The Oncomine Dx Express Test and the Genexus Dx System are currently available only in countries that accept the CE mark.