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FDA Grants Breakthrough Device Designation to Thermo Fisher Scientific's Oncomine Precision Assay to Identify IDH1 and IDH2 Mutations in Low-Grade Glioma Patients

Designation follows recent announcement on development of first companion diagnostic using the Oncomine Precision Assay on the new Ion Torrent Genexus System

CARLSBAD, Calif., June 15, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to Thermo Fisher Scientific's 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 assay, first introduced to the market as a research product in November 2019, is designed to run on the new Ion Torrent Genexus System, the first fully automated next-generation sequencing (NGS) platform with a specimen-to-report workflow that delivers comprehensive genomic profiling results in a single day.

Thermo Fisher recently announced it had expanded its strategic partnership agreement with Agios Pharmaceuticals to co-develop the companion diagnostic (CDx) for vorasidenib, an investigational, oral, brain-penetrant, dual inhibitor of mutant IDH1 and IDH2 enzymes currently under evaluation in the Phase 3 INDIGO study for IDH mutant LGG. Over time, Thermo Fisher seeks to receive premarket approval (PMA) for the Oncomine Precision Assay as a companion diagnostic for multiple therapies, as well as approval for liquid biopsy tumor profiling in lung cancer and solid tissue tumor profiling in multiple cancer types.

"Access to timely, comprehensive genomic profiling data that supports well-informed treatment decisions can be challenging under the current cancer-testing paradigm," said Dr. Alain Mita, Associate Professor of Medicine, Co-Director of the Experimental Therapeutics Program at Cedars-Sinai Medical Center. "The possibility of having multi-biomarker profiling that is generated onsite and available in about a day is game-changing for the manner and speed in which oncologists are able to determine and prescribe the most appropriate treatment for their patients."

The goal of the FDA's Breakthrough Device Program is to provide patients and health care providers with timely access to medical devices by speeding up their assessment and review, while preserving the agency's statutory standards. Once cleared under PMA, the Oncomine Precision Assay will maximize detection of guideline-recommended biomarkers, such as EGFR, ALK, KRAS, BRAF, ROS1, NTRK, RET, HER2 and others.

When combined with the Genexus System, molecular testing laboratories can generate comprehensive NGS results within the same timeframe as single-gene tests. Additionally, these features set the stage for molecular pathologists in the future to analyze NGS information in parallel with first-line testing modalities, such as immunohistochemistry (IHC).

"Breakthrough designation for the companion diagnostic is a big step forward in our endeavor to ensure that more clinicians can have quicker access to comprehensive genomic information," said Garret Hampton, president of clinical next-generation sequencing and oncology at Thermo Fisher Scientific. "Receiving this insight at the speed that the Genexus System enables can help expedite patient therapy selection, which is a critical need in the clinic today."

With its unprecedented speed to results, the Genexus System is positioned to accelerate a broad range of application areas, including oncology, infectious disease, inherited disease and reproductive health, among others. Since its launch in November 2019 as a research only solution, the integrated sequencer has also been

enabled to analyze SARS-CoV-2 samples to support epidemiology or contact tracing studies.

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