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Thermo Fisher receives BDD for Oncomine Precision Assay

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Next-Generation Sequencing solutions of Thermo Fisher Scientific help identify IDH1 and IDH2 Mutations in Low-Grade Glioma Patients

Oncomine Precision Assay on Ion Genexus NGS System

Thermo Fisher Scientific, the world leader in serving science, received breakthrough device designation for its Oncomine Precision Assay by the U.S. Food and Drug Administration (FDA). The assay can be used to identify low-grade glioma (LGG) patients with isocitrate dehydrogenase IDH1 and IDH2 mutation.

Thermo Fisher recently 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.

In November 2019, the Oncomine Precision assay was first introduced as a research product to run on Ion Torrent Genexus System – the world's first fully automated next-generation sequencing (NGS) platform with a specimen-to-report workflow that delivers comprehensive genomic profiling results in one single day.

Mr. **Amit Chopra**, managing director, India and Middle East, Thermo Fisher Scientific, said "Quick access to comprehensive genomic profiling data will open a lot of possibilities to probe accurate treatment decisions in the current treatment regimes. The multi-biomarker profiling that is generated onsite and available in about a day is game-changing for healthcare professionals, by accelerating their assessment and prescribe the most appropriate treatment for their patients faster than before."

"We have taken a great step forward by equipping the healthcare industry with faster access to comprehensive genomic information, which exemplifies our Mission to enable our customers to make the world healthier, cleaner and safer." he added.

The Ion Torrent Genexus System is the first turnkey next-generation sequencing (NGS) solution that automates the specimen-to-report workflow and delivers results in a single day with just two user touchpoints. The Oncomine Precision Assay on the Ion Torrent Genexus System is a next-generation genomic profiling solution that can allow every laboratory to

deliver a genomic profile with a one-day, hands-free workflow. Featuring the most prevalent and potentially relevant cancer driver variants across 50 genes, the Oncomine Precision Assay is ideal for fast genomic profiling in clinical cancer research. 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).

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.