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Thermo Fisher inks CDx agreement with Hengrui Therapeutics

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Thermo Fisher Scientific has signed a companion diagnostic (CDx) agreement with Hengrui Therapeutics, Inc. (HTI), a US subsidiary of Chinese pharmaceutical company Jiangsu Hengrui Medicine (JHM), to develop a CDx that will leverage the Oncomine Precision Assay, which runs on the new Ion Torrent Genexus System. Once commercialized, the CDx will be used to identify non-small cell lung cancer (NSCLC) patients who may be eligible for pyrotinib, JHM's novel, irreversible pan-HER2 tyrosine kinase inhibitor.

Under the terms of the agreement, Thermo Fisher will retain rights to commercialize the test globally and will seek approval from regulatory agencies. The company has previously announced a CDx agreement that also leverages the Oncomine Precision Assay for the Genexus System. In June the FDA granted the assay Breakthrough Device Designation to identify isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2) mutations in low-grade glioma patients.

The Oncomine Precision Assay can detect more than 50 cancer-related biomarkers from formalin-fixed paraffin-embedded (FFPE) tumor tissues or liquid biopsy specimens. It is designed to run on the Genexus System, a first-of-its-kind NGS platform that features an automated workflow with a one-day turnaround time and the lowest sample requirements on the market for detection of both DNA and RNA variants. Currently, the integrated sequencer and assay are labeled for research use only.