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CNMPA approves Agilent's PD-L1 Companion Diagnostic

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Agilent Technologies has announced that the National Medical Products Administration (NMPA, formerly the China Food and Drug Administration) has approved its PD-L1 IHC 22C3 pharmDx assay for use in China.

The assay is now approved as a companion diagnostic to identify patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (tumor proportion score [TPS]>1%) for first-line treatment with single-agent KEYTRUDA, an anti-PD-1 therapy manufactured by Merck & Co., Inc. Kenilworth, NJ, U.S.A.

Lung cancer accounts for 20% of all cancer deaths in China and is the leading cause of cancer death there[1]. NMPA approved the assay to identify advanced NSCLC patients whose tumors express PD-L1 Tumor Proportion Score (TPS) ? 1% for first-line treatment with KEYTRUDA monotherapy. KEYTRUDA, as monotherapy, recently received NMPA approval for first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 TPS ? 1% as determined by a validated test.

KEYTRUDA is a humanized monoclonal antibody that increases the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1, and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells. KEYTRUDA and other targeted immunotherapies are revolutionizing cancer treatment, and their therapeutic value is being demonstrated in NSCLC.

“Pathologists in China recognize the need for validated tests, and our companion diagnostic gives them a highly accurate tool to inform oncologists on PD-L1 expression for metastatic NSCLC patients," said Sam Raha, president of Agilent’s Diagnostics and Genomics Group. “With this approval, Agilent is excited to be able to offer the first PD-L1 CDx in the Chinese market.”

PD-L1 IHC 22C3 pharmDx is the first and only NMPA-approved companion diagnostic that has been clinically validated to aid in the identification of NSCLC patients for treatment with KEYTRUDA.