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Agilent receives FDA approval for companion diagnostic assay

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The assay is now approved as an aid in identifying patients with head and neck squamous cell carcinoma

Agilent Technologies Inc. has announced that the U.S. Food and Drug Administration (FDA) has approved its PD-L1 IHC 22C3 pharmDx assay for expanded use. The assay is now approved as an aid in identifying patients with head and neck squamous cell carcinoma (HNSCC) for treatment with KEYTRUDA (pembrolizumab), anti-PD-1 therapy manufactured by Merck.

KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ? 1) as determined by an FDA-approved test.

PD-L1 IHC 22C3 pharmDx is the only companion diagnostic FDA-approved to aid in the identification of HNSCC patients for treatment with KEYTRUDA. HNSCC is the fifth cancer type for which PD-L1 IHC 22C3 pharmDx has gained FDA approval in the United States.