US FDA approves Agilent's PD-L1 IHC 22C3 pharmDx, a companion diagnostic indicated to identify patients with epithelial ovarian, fallopian tube, or primary peritoneal carcinoma

Agilent Technologies Inc., a global leader in analytical and clinical laboratory technologies, announced that the US Food and Drug Administration (FDA) has approved PD-L1 IHC 22C3 pharmDx, Code SK006, as the only FDA-approved companion diagnostic indicated to aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (EOC), whose tumours express PD-L1 and who may be eligible for treatment with Keytruda (pembrolizumab), Merck's anti-PD-1 therapy.

PD-L1 IHC 22C3 pharmDx, Code SK006, enables pathologists to assess PD-L1 expression at the time of diagnosis, supporting informed treatment decisions in a disease where therapeutic options remain limited for many patients. This approval marks the seventh FDA approved companion diagnostic indication currently available for PD-L1 IHC 22C3 pharmDx, Code SK006, for use with Keytruda.

Nina Green, vice president and general manager of Agilent's clinical diagnostics division, stated: "Delivering effective precision oncology requires close collaboration between diagnostics and therapeutics, and this FDA approval reflects Agilent's long-standing industry partnership in companion diagnostics. We are proud to enable pathologists to identify patients with EOC who may benefit from immunotherapy. As the first immuno-oncology approval for this disease, this milestone underscores our commitment to advancing precision medicine and expanding access to innovative cancer treatments worldwide."

PD-L1 expression in EOC was evaluated using PD-L1 IHC 22C3 pharmDx, Code SK006, in the KEYNOTE-B96 clinical trial supporting its use in identifying patients who may benefit from Keytruda.

In the US, ovarian cancer caused approximately 12,730 deaths in 2025 and has a 5-year survival rate of 51.6% between 2015 to 2021.

In addition to EOC, PD-L1 IHC 22C3 pharmDx, Code SK006, is indicated in the U.S. to help physicians identify patients with non-small cell lung cancer (NSCLC), esophageal squamous cell carcinoma (ESCC), cervical cancer, head and neck squamous cell carcinoma (HNSCC), triple-negative breast cancer (TNBC), and gastric or gastroesophageal junction (GEJ) adenocarcinoma who may benefit from treatment with Keytruda.

PD-L1 IHC 22C3 pharmDx, Code SK006, was developed by Agilent in partnership with Merck & Co. (known as MSD outside the United States and Canada) as a companion diagnostic for Keytruda.

Keytruda is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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