PD-L1 IHC 22C3 pharmDx can help identify gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA¹

PD-L1 is a proven biomarker for patient response to KEYTRUDA¹,²

- Despite decreasing incidence and an increasing number of treatment options, gastric cancer continues to be a leading cause of cancer-related mortality worldwide³,⁴
- IHC testing for PD-L1 expression levels enables identification of patients most likely to benefit from anti-PD-1 monotherapy²— in KEYNOTE-059, a KEYTRUDA clinical trial, 58% of patients with gastric or GEJ adenocarcinoma had tumors that exhibited PD-L1 expression¹

PD-L1 testing should be an integral part of patient care from day ONE

Because patients with gastric cancer have poor prognosis, it is critical to assess their PD-L1 expression status upon diagnosis

- Most gastric cancer patients present at an advanced stage and are treated with upfront, systemic chemotherapy.⁴ Patients may initially respond to treatment, but many of them relapse over time,⁴ with durations of response being as short as a few months⁵
- Therefore, it is important to test for PD-L1 upon diagnosis to better inform long-term patient management and treatment

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Intended Use

For in vitro diagnostic use.

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48.

Non-Small Cell Lung Cancer (NSCLC)

PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. The specimen should be considered to have PD-L1 expression if TPS ≥ 1% and high PD-L1 expression if TPS ≥ 50%.

PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for expression cutoff values guiding therapy in specific clinical circumstances.

Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

PD-L1 protein expression in gastric or GEJ adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS ≥ 1.

PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab).