FDA Updates Prescribing Information for Keytruda and Tecentriq

Requires use of diagnostic tests for PD-L1 levels in tumor tissue from bladder cancer patients.

August 21, 2018 By Food and Drug Administration (FDA)

On August 16, 2018, the Food and Drug Administration updated the prescribing information for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq, as described below.

On August 16, 2018, the FDA approved the Dako PD-L1 IHC 22C3 PharmDx Assay (Dako North America, Inc.) as a companion diagnostic to select patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible for treatment with Keytruda. The 22C3 assay determines PD-L1 expression by using a combined positive score (CPS) assessing PD-L1 staining in tumor and immune cells. The updated indication for Keytruda is:

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA-approved test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

On July 2, 2018, the FDA approved the Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) as a companion diagnostic test to select patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible for treatment with Tecentriq. The SP142 assay determines PD L1 expression in immune cells. The updated indication for Tecentriq is:

TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥5% of the tumor area), as determined by an FDA-approved test, or

- Are not eligible for any platinum-containing therapy regardless of level of tumor PD-L1 expression

The FDA updated the prescribing information for both drugs to require use of an FDA-approved test for selection of patients being treated in the first-line setting who are cisplatin-ineligible. The second-line indications in urothelial carcinoma for both drugs remain unchanged. The tests used in the trials to determine PD-L1 expression are listed in Section 14 of each drug label.

Keytruda Prescribing Information

Tecentriq Prescribing Information

Additional information regarding Keytruda and Tecentriq is available in an FDA Drug Safety and Availability statement.

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