FDA Limits Use of Tecentriq and Keytruda for Some Urothelial Cancer Patients

Decreased survival seen in some metastatic bladder cancer patients treated with pembrolizumab or atezolizumab monotherapy.

July 9, 2018 By Food and Drug Administration (FDA)

FDA has limited the use of Tecentriq and Keytruda for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy.

The agency took this action on June 19, 2018, due to decreased survival associated with the use of Keytruda (pembrolizumab) or Tecentriq (atezolizumab) as single therapy (monotherapy) compared to platinum-based chemotherapy in clinical trials to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1).

The labels of both drugs have been revised to reflect the limitation in the indication. The indications read as follows:

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy and whose tumors express PD-L1 (Combined Positive Score ≥ 10), or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

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

- Are not eligible for cisplatin-containing therapy, 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 PD-L1 status.

On July 2, 2018, the FDA approved the Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) for PD-L1 expression in ≥ 5% IC in urothelial carcinoma tissue. The test should be used to

select patients with locally advanced or metastatic urothelial carcinoma for treatment with atezolizumab (Tecentriq, Genentech Inc.). The FDA also updated the Prescribing Information for Tecentriq to require use of an FDA-approved test for patient selection.

The tests used in the trial to determine PD-L1 expression are listed in Section 14 of each drug label. The FDA is reviewing the findings of ongoing analyses and will communicate new information regarding the PD-L1 assays and indications as it becomes available.

In patients already receiving Keytruda or Tecentriq who are responding to treatment and are cisplatin-ineligible, continuation of treatment could be considered, regardless of PD-L1 status. The FDA has not changed the indications of Keytruda and Tecentriq for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment.

Patients taking Keytruda or Tecentriq for other approved uses should continue to take their medication as directed by their health care professional.

Tecentriq Prescribing Information
Keytruda Prescribing Information

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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