Generic Name:
Pembrolizumab, atezolizumab
Trade Name:
Keytruda, Tecentriq
Company:
Merck, Genentech
Notes:

FDA is alerting health professionals, oncology clinical investigators, and the public about decreased survival associated with use of pembrolizumab or atezolizumab in clinical trials treating 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).

In two ongoing clinical trials (KEYNOTE-361 and IMVIGOR-130), patients with PD-L1 low status in the monotherapy arms had decreased survival compared with patients who received cisplatin- or carboplatin-based chemotherapy. There was no change in the adverse event profile of pembrolizumab or atezolizumab.

Both Merck, manufacturer of pembrolizumab, and Genentech, manufacturer of atezolizumab, have stopped enrolling patients whose tumors have PD-L1 low status to the pembrolizumab or atezolizumab monotherapy arms.

Both agents are currently approved for treatment of locally advanced or metastatic urothelial carcinoma patients who are not eligible for cisplatin-containing chemotherapy, irrespective of PD-L1 status.

Patients taking pembrolizumab or atezolizumab for other approved uses should continue to take their medication as directed by their health professional.

Health professionals should be aware that the populations enrolled in the ongoing clinical trials were eligible for platinum-containing chemotherapy and therefore differ from those enrolled in the trials that led to the accelerated approvals of both pembrolizumab or atezolizumab for treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

FDA recommends providers select patients for treatment of locally advanced or metastatic urothelial cancer using the criteria described in Section 14 of each label. These criteria supported the approvals for pembrolizumab and atezolizumab for initial monotherapy in cisplatin-ineligible patients.

The agents are also currently FDA approved for treatment of multiple types of other cancers.

Medication Monitor Categories:
Alerts and Recalls