Keytruda® (pembrolizumab), Tecentriq® (atezolizumab) – Safety communication

- On May 18, 2018, the FDA announced that decreased survival is associated with the use of Keytruda (pembrolizumab) or Tecentriq (atezolizumab) as monotherapy 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).
    - Both Keytruda and Tecentriq are currently approved under accelerated approval for the treatment of locally advanced or metastatic urothelial carcinoma patients who are not eligible for cisplatin-containing chemotherapy, irrespective of PD-L1 status.
- Keytruda is also indicated for the treatment of patients with melanoma, non-small cell lung cancer (NSCLC), head and neck cancer, classical Hodgkin lymphoma, microsatellite instability-high cancer, and gastric cancer.
- Tecentriq is also indicated for the treatment of patients with metastatic NSCLC.
- Patients taking Keytruda or Tecentriq for other approved uses should continue to take their medication as directed by their health care professional.
- Health care 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 Keytruda and Tecentriq in the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
- The FDA recommends that providers select patients for the treatment of locally advanced or metastatic urothelial cancer using the criteria described in section 14 of each label. These criteria supported the approvals for Keytruda and Tecentriq for initial monotherapy in cisplatin-ineligible patients.
- The safety update is based on data from two ongoing clinical trials (KEYNOTE-361 and IMVIGOR-130). The Data Monitoring Committees' (DMC) early reviews found patients in the monotherapy arms of both trials with PD-L1 low status had decreased survival compared to patients who received cisplatin- or carboplatin-based chemotherapy.
    - There was no change in the adverse event profile of Keytruda or Tecentriq.
    - Both Merck, the manufacturer of Keytruda, and Genentech, the manufacturer of Tecentriq, have stopped enrolling patients whose tumors have PD-L1 low status to the Keytruda or Tecentriq monotherapy arms per the DMCs' recommendations.
- The ongoing clinical trials compare platinum-based chemotherapy combined with Keytruda or Tecentriq to platinum-based chemotherapy alone. Both trials enrolled a third arm of monotherapy with Keytruda or Tecentriq to compare to platinum-based chemotherapy alone.

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- The monotherapy arms remain open only to patients whose tumors have PD-L1 high status.
- The combination arms and the chemotherapy arms of both studies also remain open.
- The FDA is reviewing the findings of the ongoing clinical trials and will communicate new information as necessary.

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