SAFETY COMMUNICATION

21-10-2018

Risk of Myocarditis Associated With the Use of Atezolizumab

The Saudi Food and Drug Authority (SFDA) would like to notify the healthcare professionals (HCPs) about the identified risk of myocarditis (particularly immune related myocarditis) associated with the use of atezolizumab.

Atezolizumab is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma. Atezolizumab therapy is mainly suitable for patients who have disease progression during/following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant/adjuvant treatment with platinum-containing chemotherapy.

In clinical trials, myocarditis occurred in less than 0.1% of all cohorts treated with atezolizumab. The disproportionality (data mining) between the observed and the expected reporting rate of a drug-ADR pair has been measured by using the World Health Organization (WHO) ADR database (Vigilyze®). The result showed that the combination of "atezolizumab" and the risk "myocarditis" has been observed more than expected when compared to other medications in the database and this observation was statically significant.

Accordingly, the SFDA strongly recommends monitoring patients using atezolizumab for signs and symptoms of myocarditis. Treatment with atezolizumab should be hold for grade 2 myocarditis, and immediate treatment with systemic corticosteroids (prednisone or equivalent) must be started. In addition, therapy should be permanently discontinued for grade 3 and 4 myocarditis.

Finally, the SFDA requested the Marketing Authorization Holder (MAH) to update the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) to address the current risk.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 01 2038222 ext. 2317-2356-2340.
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa