SFDA
Safety communication

[27 /02/2024]

Serious Risk of T-cell Malignancy Associated with the Use of Chimeric Antigen Receptor (CAR) T cell Immunotherapies

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals about the potential risk of T-cell malignancy associated with the use of chimeric antigen receptor (CAR) T cell Immunotherapies.

SFDA reviewed data on secondary malignancies related to T-cells, including T-cell lymphoma and leukemia, for the current three approved CAR T cell immunotherapies in Saudi Arabia: CILTACABTAGENE AUTOLEUCEL (CARVYKTI®), TISAGENLECLEUCEL (KYMRIAH®), and AXICABTAGENE CILOLEUCEL (YESCARTA®).

CAR T cell immunotherapies are approved for the treatment of adult patients with refractory or relapsing large B-cell lymphoma, adults with relapsed or refractory follicular lymphoma (FL), adults with relapsed or refractory multiple myeloma, pediatric and young adult patients with B-cell Acute lymphoblastic leukemia (ALL). Secondary malignancies were mentioned in the warnings and precautions section in the local product information for all three CAR T-cell therapies.

We reviewed the current evidence, including published literature and post-marketing data to assess the association between the potential risk of T-cell malignancies with CAR T-cell immunotherapy. Our review found one clinical trial and two published case reports suggesting a possible association between secondary T -cell malignancy with CAR T-cell immunotherapy. In addition, we identified 10 serious spontaneous case reports of T-cell malignancies in the World Health Organization (WHO) database with KYMRIAH® and YESCARTA® (5 cases each).

Therefore, the SFDA requests a comprehensive signal evaluation report from the Marketing Authorization Holders of KYMRIAH® and CARVYKTI®. In addition, the SFDA requests to update the product information of YESCARTA® as follows:

4.4 Special warnings and precautions for use:

Secondary Malignancies

The T-cell malignancies have occurred following treatment with BCMA- and CD19- directed genetically modified autologous T cell immunotherapies, including YESCARTA. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes.

4.8 Undesirable effects:

Post-marketing Experience:

Neoplasms: T cell malignancies

Call for reporting:
The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:
The National Pharmacovigilance Centre (NPC):
Call Center: 19999
Website: https://ade.sfda.gov.sa

RMM: