SFDA
Safety communication

[02/06/2024]

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

In reference to the last safety communication released by the Saudi Food and Drug Authority (SFDA) on 27/2/2024 to notify healthcare professionals about the potential risk of T-cell malignancy associated with the use of Chimeric Antigen Receptor (CAR) T cell Immunotherapies.

In this communication, the SFDA requested an update the product information of YESCARTA® to include the risk of a secondary T-cell malignancy and a comprehensive signal evaluation report from the Marketing Authorization Holders of KYMRIAH® and CARVYKTI® regarding the risk of secondary T-cell malignancy.

The current three approved CAR T cell immunotherapies in Saudi Arabia are: CILTACABTAGENE AUTOLEUCEL (CARVYKTI®), TISAGENLECLEUCEL (KYMRIAH®), and AXICABTAGENE CILOLEUCEL (YESCARTA®).

Considering current evidence and the results of the assessment reports submitted by the MAHs, the SFDA also requests to update the product information of KYMRIAH® and CARVYKTI® as following:

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. 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):
Fax: +966-11-205-7662 SFDA
Call Center: 19999
Website: https://ade.sfda.gov.sa

RMM: