SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually m ore than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

11-03-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Teclistamab and the Risk of Tumour lysis syndrome

The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of ***Tumour lysis syndrome*** *associated with the use of* ***Teclistamab****. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Teclistamab is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. [1] Tumor lysis syndrome refers to the constellation of metabolic disturbances that occurs when large numbers of neoplastic cells are killed rapidly, leading to the release of intracellular ions and metabolic byproducts into the systemic circulation. Clinically, the syndrome is characterized by rapid development of hyperuricemia, hyperkalemia, hyperphosphatemia, hypocalcemia, and acute kidney injury. [2] The aim of this review is to evaluate the risk of Tumour lysis syndrome associated with the use of Teclistamab and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between Tumour lysis syndrome and Teclistamab use. The search conducted on January 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 24 global case-reports. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on all extracted ICSRs. [4] Among them, 3 cases were possibly linked to Teclistamab, while the remaining 21 cases were unable to be assessed due to lack of important information such as temporal relationship.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values

indicates less statistical association. The IC result is (4.7) for this drug/ADR combination which reflects strong positive statistical association. [3]

Conclusion

The weighted cumulative evidence from assessed cases and disproportionality analysis suggests a potential causal association between Teclistamab and Tumor Lysis Syndrome. Healthcare professionals and regulatory authorities should be aware of this potential risk in patients receiving the drug.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (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
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

1- Dailymed.nlm.nih.gov. (n.d.). DailyMed - TECVAYLI- teclistamab injection. [online] Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=54e0f974-ccee-44ea-9254-40e9883cee1e.

2- Tumor Lysis Syndrome: Practice Essentials, Pathophysiology, Etiology. (2019). eMedicine. [online] Available at: https://emedicine.medscape.com/article/282171-overview.

3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org

4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at https://www.who.int/publications/m/item/WHO-causality-assessment .