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"

29-09-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Risankizumab and the Risk of Neutropenia

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

Introduction

Risankizumab is indicated for the treatment of: plaque psoriasis, active psoriatic arthritis in adults, Crohn's disease in adults and active ulcerative colitis. It is a humanized IgG1 monoclonal antibody that selectively binds to the p19 subunit of human IL-23 cytokine and inhibits its interaction with the IL-23 receptor. It inhibits the release of pro-inflammatory cytokines and chemokines. [1] Neutropenia is a condition characterized by an abnormally low number of neutrophils, which are granulated leukocytes crucial for the initial immune response to inflammation and infection. Neutrophils ingest, kill, and digest invading microorganisms such as fungi and bacteria. [2] The aim of this review is to evaluate the risk of Neutropenia associated with the use of Risankizumab 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 Neutropenia and Risankizumab use. The search conducted on August 2025.

Results

Cases 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 83 global case-reports while only one local case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted 30 ICSRs. [4] Among them, seven cases were assessed as probably or possibly linked to Risankizumab, two cases were considered unlikely, while twenty-one cases could not be assessed due to insufficient information.

Literature: The signal team conducted a literature search to identify publications linking neutropenia to Risankizumab. The search identified two publications suggesting a potential association. [5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Risankizumab and Neutropenia. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

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:

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2- Rout P, Reynolds SB, Zito PM. Neutropenia. [Updated 2024 Jun 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507702/

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5- Okada, Y., Kajiyama, K., Ishiguro, C., Nonaka, T., Komaki, T., Kuga, W., ... & Uyama, Y. (2024). Risk of neutropenia in psoriasis patients prescribed anti-IL-23 antibody in comparison with anti-IL-17 antibody or adalimumab based on real-world data from the MID-NET® in Japan. Journal of Dermatological treatment, 35(1), 2373826.

6- AbbVie. (2020). A study to evaluate the efficacy and safety of risankizumab in adult participants with moderate to severe plaque psoriasis (M16-176) [Clinical study report summary]. AbbVie. https://www.abbvie.com/content/dam/abbvie-dotcom/uploads/PDFs/results-summaries/Clinical_Study_M16-176_English.pdf