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"

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Saudi Food and Drug Authority (SFDA) – Safety Signal of Tofacitinib and the Risk of Hair loss (Alopecia)

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

Introduction

Tofacitinib is approved for the treatment of moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PA), ulcerative colitis (UC), and polyarticular course juvenile idiopathic arthritis (pcJIA). It is a second-generation selective Janus kinase (JAK) inhibitor targeting the JAK1 enzyme. [1] Alopecia is the medical term for hair loss, which can occur in a single area or several areas of your head and body. Types of alopecia include male or female pattern hair loss and alopecia areata. Alopecia can be caused by stress, genetics, health conditions, medicines or damage to your hair. Sometimes your hair will grow back, but it may fall out again or never grow back. There are treatment options for alopecia, but they don't always work and some people may need to learn to live with hair loss. [2] The aim of this review is to evaluate the risk of Hair loss associated with the use of Tofacitinib 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 potential link between Hair loss and Tofacitinib use.

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 2392 global case reports while 1 local case found which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3]. The author applied Who Causality assessment tool on the extracted cases with completeness 0.9 and above (31 cases). Among them, 4 cases were probably linked to Tofacitinib, 12 cases resulted in possible association, and 3 cases resulted in unlikely association, while the remaining 12 cases lacked sufficient information for a proper assessment.

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 (IC= 1.2) for this drug/ADR combination which reflects positive statistical association. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Baricitinib. The search identified multiple relevant studies suggesting a possible association between the drug and this alopecia risk. [4][5]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, disproportionality analysis and literature are suggestive for causal association between Tofacitinib and Hair loss. 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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