Saudi Food & Drug Authority (SFDA)

SAFETY COMMUNICATION

9 August 2018

Potential Risks of Hematological Relapses and Deaths Associated with Long-Term Use of Azithromycin Following Hematopoietic Stem Cell Transplant

The SFDA would like to notify healthcare professionals (HCPs) that the long-term use of Azithromycin as prophylactic treatment to prevent bronchiolitis obliterans syndrome (BOS) in patients with hematologic malignancies who undergo hematopoietic stem cell transplant (HSCT) is lacking scientific evidence, due to an increased risk of hematological relapses and deaths.

The promoter for releasing this warning statement was the findings of French ALLOZITHRO trial[1]. The main objective of this study was to investigate the efficacy of long-term azithromycin in preventing BOS after allogeneic HSCT. The trial was terminated at an early stage after dramatic increase in the number of reported hematological relapses and deaths in azithromycin group compared with placebo. The study concluded that long-term azithromycin use following HSCT may potentiate risks that exceed the anticipated treatment benefits.

BOS is an inflammatory condition that causes irreversible damage to the bronchioles of the lungs. This condition deemed serious complication following allogeneic HSCT. Having that been said, azithromycin is not approved as prophylactic measure for BOS.

Currently, the National Pharmacovigilance Center (NPC) is reviewing additional data concerning the safety concern and conclusive recommendations will be released as soon as they become available. Meanwhile, the SFDA advises HCPs not to prescribe azithromycin for long-term use as prophylaxis of BOS to patients who undergo HSCT.

Reference:

1. Bergeron A, Chevret S, Granata A, et al. Effect of azithromycin on airflow decline-free survival after allogeneic hematopoietic stem cell transplant: the ALLOZITHRO randomized clinical trial. JAMA 2017; 318(6):557-566.

Report Adverse Drug Events (ADEs) to the SFDA

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:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
SFDA Call Center: 19999
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa
Webpage: www.sfda.gov.sa/npc