SFDA
Safety Communication

[15/06/2021]

Potential Risk of Interstitial Lung Disease Associated with the Use Sunitinib

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about the potential risk of interstitial lung disease associated with the use of sunitinib.

Sunitinib is an inhibitor of multiple protein tyrosine kinases (TKI); it targets vascular endothelial growth factor receptor (VEGFR) -1, VEGFR-2, VEGFR-3, platelet-derived growth factor-α receptor (PDGFR-α), PDGFR-β. Sunitinib was approved by the SFDA to treat gastrointestinal stromal tumor, metastatic renal cell carcinoma and pancreatic neuroendocrine tumors.

Interstitial lung diseases include a broad spectrum of conditions, characterized by inflammation or fibrosis of the alveolar wall with impairment of gas exchange. Signs and symptoms may include dyspnea, hypoxia, cough, dyspnea, wheezing, chest pain or interstitial infiltrates on chest radiology.

We reviewed published literature and post marketing databases on the potential risk of interstitial lung disease with the use of sunitinib. Our review found five published case-reports and two observational studies suggesting a potential link between the use of sunitinib and interstitial lung disease. In addition, we identified 115 spontaneous case reports of interstitial lung disease with the use of sunitinib in the World Health Organization (WHO) database. The cases involved 71 males and 23 females, the rest are unknown. Age ranges were between 6 to 116 years old. Time to onset ranges from 5 days up to 2 years after the use of sunitinib. 110 cases out of 115 were categorized as serious cases and fatality was reported in 23 of the cases.

The mechanisms of TKI-induced interstitial lung disease remain debatable. The main hypotheses for such involve a hypersensitivity reaction, the pharmacological action of the TKI itself, and induced pulmonary fibrosis and inflammatory cell infiltration upon inhibition of PDGFR-A. In addition, the combination of TKI and radiotherapy may lead to additional toxicity when visceral organs are within the radiation field.

Therefore, the SFDA requests to update the product information of sunitinib containing products by adding interstitial lung disease as a postmarking adverse event. The SFDA advises healthcare professional discontinue the sunitinib therapy if a patient developed interstitial lung disease.

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
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa