

# Direct Healthcare Professional Communication



**10-April-2018**

**Subject:** Cases of Myocarditis Reported with  
TECENTRIQ® (Atezolizumab)

Dear Healthcare Professional,

Roche Products Saudi Arabia (RPSA) in agreement with the Saudi Food and Drug Authority would like to inform you of important new safety information for TECENTRIQ® indicated for the treatment of locally advanced or metastatic urothelial carcinoma, or metastatic non-small cell lung cancer (for detailed information about indications, please see the package insert).

## **Serious Risk with the Use of TECENTRIQ®**

- Cases of myocarditis have been reported in cancer patients receiving TECENTRIQ® treatment in clinical trials. A cumulative analysis of the company safety database, which includes data from clinical trials and post-marketing setting (data cut-off date 20 February 2017), identified 2 non-fatal cases of myocarditis, including one case with biopsy confirmation. Approximately 8,000 clinical trial patients and 5,000 post-marketing patients have been exposed to TECENTRIQ® to date.
- The mechanism of action of TECENTRIQ® permits the possibility of developing myocarditis. Moreover, immune-mediated myocarditis is listed on the labels of similar-in-class drugs.

## **Prescriber Action**

- It is recommended that TECENTRIQ® should be permanently discontinued for all grades of myocarditis. Corticosteroids and/or additional immunosuppressive agents should be administered as clinically indicated.

**The information in this letter has been approved by Saudi Food & Drug Authority (SFDA).**

**Call for reporting**

Please report any suspected adverse reactions associated with the use of TECENTRIQ® (Atezolizumab) in accordance with the national requirements via the national spontaneous reporting system, to:

**Roche Products Saudi Arabia L.L.C.**

Saudi Arabia P.O. Box 3683 Jeddah 23414

Le Prestige Mall

King Abdulaziz Branch Rd

Direct Tel. +966 12211 4618

Mobile: +966 5678 44 692

Email: [jeddah.drug\\_safety@roche.com](mailto:jeddah.drug_safety@roche.com)

Local Safety Responsible: [Hassan.linjawi@roche.com](mailto:Hassan.linjawi@roche.com)

[www.roche.com](http://www.roche.com)

**The National Pharmacovigilance and Drug Safety Centre (NPC)**

Land Line: 19999.

Website: [https://:ade.sfda.gov.sa](https://ade.sfda.gov.sa)

Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

Fax: +96612057662.

Sincerely,

Hassan Linjawi, PharmD.

Qualified Person for Pharmacovigilance (QPPV)



10 April 2019