



Date: September 2<sup>nd</sup>, 2018

## Direct Healthcare Professional Communication

### TECENTRIQ® (atezolizumab): A New Important Identified Risk: Nephritis

Dear Healthcare professional,

Roche Products Saudi Arabia L.L.C. in agreement with the *Saudi Food and Drug Authority* would like to inform you of the following:

#### *Summary*

- ***Immune-related nephritis has now been added as a new important identified risk associated with the use of TECENTRIQ® (atezolizumab).***
- ***It is recommended that TECENTRIQ® (atezolizumab) should be withheld for moderate (Grade 2) immune-related nephritis and permanently discontinued for severe nephritis (Grade 3 and 4). Please refer patient to renal specialist and consider renal biopsy and supportive measures as indicated. Corticosteroids and/or additional immunosuppressive agents should be administered as clinically indicated.***

#### *Background on the safety concern*

Immune-related nephritis is a relatively rare complication of checkpoint inhibitors (CPI) therapy with the most common reported underlying pathology being acute tubulo-interstitial nephritis (ATIN). The most common presentation is asymptomatic increase in creatinine levels. In the absence of alternative etiologies (e.g. prerenal and postrenal causes, and concomitant medications), immune-related nephritis is defined as renal dysfunction requiring steroids treatment and/or confirmed by biopsy.

A cumulative analysis was performed and identified cases of immune-related nephritis including biopsy-confirmed cases, in patients receiving atezolizumab. Approximately 17,215 clinical trial patients and 20,783 post-marketing patients have been exposed to TECENTRIQ® (atezolizumab) to date. Based on the assessment of the available data, immune-related nephritis is considered as an important identified risk for TECENTRIQ® (atezolizumab).



### *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>

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

Fax: +96612057662.

### *Company contact point*

Should you have any questions regarding the use of **TECENTRIQ® (atezolizumab)**, please feel free to contact us at:

Local Medical Information:

[Jeddah.medinfo@roche.com](mailto:Jeddah.medinfo@roche.com)

+966 54 531 8 530

Sincerely,

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

*Hassan Linjawi, QPPV Roche Saudi Arabia*

*Sep 2018*