July 30, 2018

*Roche Products (India) Pvt. Ltd.*
1503, 15th Floor, "The Capital"
Plot No. C-70, Behind ICICI Bank
Bandra Kurla Complex, Bandra (E)
Mumbai 400 051, India

**Product:** Atezolizumab Injection 1200mg/20ml (Tecentriq®)

**Direct Healthcare Professional Communication**

**TECENTRIQ® (Atezolizumab): A New Important Identified Risk: Nephritis**

**Dear Healthcare professional,**

F. Hoffmann-La Roche Ltd., 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 Injection).***
- ***It is recommended that Tecentriq® (Atezolizumab Injection) 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 Injection) to date. Based on the assessment of the available data, immune-related nephritis is considered as an important identified risk for Tecentriq® (Atezolizumab Injection).



**Roche Products (India) Pvt. Ltd.**

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## Call for Reporting

Healthcare professionals are requested to report any side effect experienced by patient while on Tecentriq® (atezolizumab Injection) therapy directly to us on india.drugsafety@roche.com. Following which the same will be updated in our drug safety database and also will be communicated to CDSCO office according to the adverse event reporting regulatory requirements.

## Company Contact Information

Roche is working closely with Health Authority to update the product label (Product Prescribing Information) to reflect the risk of immune-related nephritis. Please refer current Prescribing Information of Tecentriq® (Atezolizumab Injection) for a complete discussion of the other risks associated with Tecentriq® (Atezolizumab Injection).

If you have any questions or concerns about the information contained in this letter or the safe and effective use of Tecentriq®, please feel free to contact us at: +91-8879021826 or india.medinfo@roche.com.

Yours sincerely,
**Roche Products (India) Pvt. Ltd.**

**Dr. Anil Kukreja**
Medical Director



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