



August 9, 2018

Direct Healthcare Professional Communication

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

Dear Healthcare professional,

Roche in agreement with the European Medicines Agency (EMA) 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

Health care professionals should report any adverse events suspected to be associated with the use of TECENTRIQ® (atezolizumab) to: cac.farmacovigilancia@roche.com. Alternatively, this information may be reported in accordance with your national spontaneous reporting system.



Company contact point

Roche is working to update the product label to reflect the risk of immune-related nephritis.

Should you have any questions regarding the use of TECENTRIQ® (atezolizumab), please feel free to contact us at: cac.medical_info@roche.com

Sincerely,

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