Date: 5 December 2018

Direct Healthcare Professional Communication

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

Dear Healthcare Professional,

Roche Products (New Zealand) Limited ("Roche") would like to inform you of safety updates to Tecentriq.

Summary

- ***Immune-related nephritis has now been added as a new important identified risk associated with the use of Tecentriq®***
- ***It is recommended that Tecentriq® 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® to date. Based on the assessment of the available data, immune-related nephritis is considered as an important identified risk for Tecentriq®.

Roche Products (New Zealand) Limited
98 Carlton Gore Road
Newmarket
Auckland 1023
PO Box 109113
Newmarket,
Auckland 1149
New Zealand
Phone :+64 9 523 9400
Fax: +64 9 523 9465
Toll Free: 0800 656 464

Further Information

The Special Warnings and Precautions for Use, Undesirable Effects and Dose and Method of Administration sections of the Data Sheet have been updated in line with this new information. Before prescribing, please review the full Tecentriq Data Sheet available at www.medsafe.govt.nz.

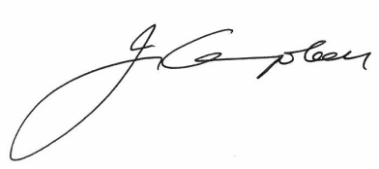
If you have any questions or require additional information regarding the use of Tecentriq please contact Roche Medical Information on 0800 276 243 or email at auckland.medinfonz@roche.com.

Reporting Adverse Events

Roche will continue to monitor the safety of Tecentriq through established reporting mechanisms and notify regulatory authorities as per current regulations.

Please report any suspected adverse events via email to Roche Drug Safety at nz.drugsafety@roche.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at https://nzphvc.otago.ac.nz/reporting or by email to nzphvc@otago.ac.nz.

Sincerely,



Jan Campbell

Medical Director

Roche Products (New Zealand) Limited
98 Carlton Gore Road
Newmarket
Auckland 1023
PO Box 109113
Newmarket,
Auckland 1149
New Zealand
Phone :+64 9 523 9400
Fax: +64 9 523 9465
Toll Free: 0800 656 464