13 June 2019

Direct Healthcare Professional Communication

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

Dear Healthcare professional,

Roche Products (New Zealand) Limited ("Roche") in consultation with the New Zealand Medicines and Medical Devices Authority (MEDSAFE) would like to inform you of safety updates to Tecentriq.

Summary

- ***Immune-related myositis 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 or severe (Grade 2 or 3) immune-related myositis and permanently discontinued for recurrent severe or life-threatening myositis (recurrent Grade 3 and Grade 4).***
- ***As clinically indicated, please refer the patient to rheumatologist and/or neurologist and consider muscle biopsy and supportive measures.***

Treatment

a) Corticosteroid treatment with 1-2 mg/kg/day IV methylprednisolone or, higher-dose bolus if severely compromised (weakness severely limiting mobility, cardiac function, respiratory function, dysphagia).

b) Consider additional immunosuppressive agents for > grade 2 events, severely compromised patients, or if event does not improve after initial corticosteroids.

Background on the safety concern

Myositis or inflammatory myopathies are a group of disorders sharing the common feature of inflammatory muscle injury; dermatomyositis and polymyositis are amongst the most common disorders. Diagnosis is based on clinical (muscle weakness, muscle pain, skin rash in dermatomyositis), biochemical (serum creatine-kinase increase), and imaging (electromyography/MRI) features, and is confirmed with a muscle-biopsy.

A comprehensive analysis was performed across the Tecentriq program and identified cases of immune-related myositis, including biopsy-confirmed, in patients that have received atezolizumab. There were 4 cases of myositis with a fatal outcome with some cases suggestive of cardiac involvement (myocarditis or AV blocks). The incidence of myositis observed across the atezolizumab monotherapy clinical programme was <0.1%. Based on

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

the assessment of all available data, immune-related myositis is considered an important identified risk for Tecentriq.

Further Information

The Dose and Method of Administration, Special Warnings and Precautions for Use and Undesirable Effects 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