Date: 31 January 2019

*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 Safety Update Identified Risk: Immune-related Myositis**

Dear Healthcare professional,

F. Hoffmann-La Roche Ltd. in agreement with the European Medicines Agency [EMA] would like to inform you of the following:

*Summary*

- ***Immune-related myositis 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 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). Please refer the patient to rheumatologist and/or neurologist and consider muscle biopsy and supportive measures as clinically indicated. Corticosteroids 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) and/or additional immunosuppressive agents should be administered for > grade 2 events 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 cases, in patients that have received Atezolizumab Injection. There were 4 cases of myositis with a fatal outcome with some cases suggestive of cardiac involvement (myocarditis or AV blocks). Approximately 19,323 clinical trial patients and 28,975 post-marketing patients have been exposed to TECENTRIQ® (Atezolizumab Injection) as of Nov 17, 2018. The incidence of myositis observed across the Atezolizumab monotherapy clinical programme was <0.1%. Based on the



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assessment of all available data, immune-related myositis is considered an important identified risk for TECENTRIQ® (Atezolizumab Injection).

*Call for reporting*

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Health care professionals should report any adverse events and special situation associated with the use of TECENTRIQ® (Atezolizumab Injection) therapy directly to us on 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 authorities to update the product label to reflect the risk of immune-related myositis. To further minimize this risk, health care professionals should follow the management guidance detailed above. The benefit-risk profile of Atezolizumab Injection in the approved indications remains favourable.

If you have any questions or concerns about the information contained in this letter or the safe and effective use of TECENTRIQ® (Atezolizumab Injection), please contact us +91-8879021826 or india.medinfo@roche.com.

Yours Sincerely,

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

**Dr. Anil Kukreja**

Medical Director

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