Gayane Ghazaryan, Medical Manager

Local Safety Responsible of Hoffmann-La Roche products in Armenia

Direct Healthcare Professional Communication

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

Dear Healthcare professional,

F. Hoffmann-La Roche Ltd. in agreement with the European Medicines Agency> and <the National Competent Authority 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).***
- ***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). 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

Tecentriq® (atezolizumab) as monotherapy is indicated for:

- the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):
  - after prior platinum-containing chemotherapy, or;
  - who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression ≥ 5%.
- the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with EGFR activating mutations or ALK-positive tumour mutations should also have received targeted therapy before receiving Tecentriq.

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.