Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): axicabtagene ciloleucel

Procedure No. EMEA/H/C/PSUSA/00010703/201904

Period covered by the PSUR: 18 October 2018 – 17 April 2019
Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for axicabtagene cilooleucel, the scientific conclusions of CHMP are as follows:

A causal relationship between spinal cord lesions and axicabtagene cilooleucel was confirmed, based on the evidence from two clinical trial cases; one case with an event of quadriplegia (in the setting of myelitis) and second case with events of muscular weakness and leukoencephalopathy, and one spontaneous case report with an event of spinal cord oedema. These events were considered as syndromes of neurologic toxicity, an important identified risk of axicabtagene cilooleucel use. Muscular weakness and leukoencephalopathy are listed in the axicabtagene cilooleucel product information. The PRAC considers that the product information of axicabtagene cilooleucel should be amended to reflect the risk of spinal cord oedema, myelitis and quadriplegia associated with axicabtagene cilooleucel therapy.

A causal relationship between dysphagia and axicabtagene cilooleucel was confirmed, based on the evidence from 15 post-marketing cases and 4 clinical trial cases of dysphagia. Dysphagia is a recognised symptom of encephalopathy which is currently listed in the product information; however, dysphagia can lead to serious complications and may require specific clinical measures. The PRAC considers that the product information of axicabtagene cilooleucel containing products should be amended to reflect the risk of dysphagia associated with axicabtagene cilooleucel therapy.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for axicabtagene cilooleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing axicabtagene cilooleucel is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.