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Committee for Medicinal Products for Human Use (CHMP)

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Scientific conclusions

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

A causal relationship between spinal cord lesions and axicabtagene ciloleucel 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 ciloleucel use. Muscular weakness and leukoencephalopathy are listed in the axicabtagene ciloleucel product information. The PRAC considers that the product information of axicabtagene ciloleucel should be amended to reflect the risk of spinal cord oedema, myelitis and quadriplegia associated with axicabtagene ciloleucel therapy.

A causal relationship between dysphagia and axicabtagene ciloleucel 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 ciloleucel containing products should be amended to reflect the risk of dysphagia associated with axicabtagene ciloleucel 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 ciloleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing axicabtagene ciloleucel 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.