20 July 2023
EMA/CHMP/321765/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tevimbra

tislelizumab

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tevimbra[2], intended for the treatment of oesophageal squamous cell carcinoma. The applicant for this medicinal product is Novartis Europharm Limited.

Tevimbra will be available as a 100 mg concentrate for solution for infusion. The active substance of Tevimbra is tislelizumab, an antineoplastic agent (ATC code: L01FF09). Tislelizumab is a humanised IgG4 variant monoclonal antibody that potentiates T cell responses, including anti-tumour responses, through blockade of PD-1 binding to PD-L1 and PD-L2 ligands.

The benefit of Tevimbra is an improvement in overall survival in patients with advanced or metastatic oesophageal squamous cell carcinoma, as shown in an open-label, randomised phase 3 study comparing Tevimbra with ICC. The most common side effect is anaemia.

The full indication is:

> Tevimbra as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy.

Tevimbra should be prescribed by physicians experienced in the treatment of cancer.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained.

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