25 July 2024
EMA/CHMP/305308/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Loqtorzi

toripalimab

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Loqtorzi, intended for the treatment of nasopharyngeal carcinoma and oesophageal squamous cell carcinoma.

The applicant for this medicinal product is TMC Pharma (EU) Limited.

Loqtorzi will be available as a 240 mg concentrate for solution for infusion. The active substance of Loqtorzi is toripalimab, an antineoplastic agent (ATC code: L01FF13). Toripalimab is a humanized IgG4 kappa monoclonal antibody that binds to programmed death receptor-1 (PD-1). It blocks the binding of programmed death ligand-1 (PD-L1) and PD-L2 to PD-1, thereby preventing the inhibition of immune responses via the PD-1 pathway, including anti-tumour immune responses.

The benefit of Loqtorzi is an improved progression-free survival (PFS) in patients with locally advanced nasopharyngeal carcinoma and advanced or metastatic oesophageal squamous cell carcinoma, as shown in two studies comparing Loqtorzi with standard of care. The most common side effects with Loqtorzi in combination with platinum containing chemotherapy are anaemia, leukopenia, neutropenia, thrombocytopenia, nausea, vomiting, decreased appetite, rash, fatigue, abnormal liver function test, hypothyroidism, constipation and neuropathy.

The full indication is:

> LOQTORZI, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma.
>
> LOQTORZI, in combination with cisplatin and paclitaxel, is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

Treatment with Loqtorzi should be prescribed and supervised by physicians experienced in the treatment

[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

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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.