



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMA/CHMP/62536/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Imdylltra

tarlatamab

On 26 March 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imdylltra², intended for the treatment of extensive-stage small cell lung cancer (SCLC).

The applicant for this medicinal product is Amgen Europe B.V.

Imdylltra will be available as a 1 mg and 10 mg powder for concentrate and solution for solution for infusion. The active substance of Imdylltra is tarlatamab, an antineoplastic agent (ATC code: L01FX33). Tarlatamab is a bispecific T-cell engager targeting DLL3, an oncogenic protein aberrantly expressed by SCLC tumour cells, and CD3 expressed by T cells. This activates T cells and leads to the production of inflammatory cytokines and the release of cytotoxic proteins, resulting in tumour cell death.

The benefits of Imdylltra are a statistically and clinically significant improvement in overall survival (OS), and a 40% reduction in the risk of death with Imdylltra compared with the active comparator arm, based on an ongoing, randomised, open-label, multicentre phase 3 study comparing tarlatamab to standard of care in adults with relapsed SCLC after platinum-based first line chemotherapy.

The most common side effects with Imdylltra include cytokine release syndrome (CRS), decreased appetite and pyrexia.

The full indication is:

IMDYLLTRA is indicated as monotherapy for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC), who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy.

Imdylltra treatment should be initiated under the direction of and supervised by physicians experienced in the use of cancer therapy. It should be administered in an appropriate healthcare facility.

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



Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.