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Amgen Receives EC Approval for IMDYLLTRA in Extensive-Stage Small Cell Lung Cancer

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The DLL3-targeting T-cell engager showed a survival benefit over chemotherapy in patients whose disease progressed after first-line platinum-based treatment.

Amgen has received European Commission marketing authorisation for IMDYLLTRA, or tarlatamab, as monotherapy for adults with extensive-stage small cell lung cancer who require systemic therapy after disease progression on or after first-line platinum-based chemotherapy.

The approval addresses a high-unmet-need oncology setting where patients have limited options after relapse. Small cell lung cancer is an aggressive tumour type associated with rapid progression, high relapse rates and historically poor outcomes following first-line therapy.

IMDYLLTRA is a first-in-class targeted immunotherapy designed to bind DLL3 on tumour cells and CD3 on T cells, activating T cells to kill DLL3-expressing cancer cells. DLL3 is expressed on the surface of small cell lung cancer cells in up to 96 percent of patients, while being minimally expressed on healthy cells.

The approval was based on the global Phase 3 DeLLphi-304 trial, which demonstrated that IMDYLLTRA reduced the risk of death by 40 percent versus standard-of-care chemotherapy. Median overall survival was 13.6 months with IMDYLLTRA compared with 8.3 months with chemotherapy.

The safety profile was consistent with the therapy’s known profile. The most common adverse reactions included cytokine release syndrome, decreased appetite, fever, altered taste, constipation, anaemia, fatigue and nausea. The product requires monitoring during early dosing, reflecting the operational considerations associated with T-cell engager therapy.