

Annex No. 1 to Art. 7a, para. 2									
Marketing Authorisation Holder	Amgen Europe B.V., The Netherlands								
Name of medicine	Imdylltra®								
ATC code	L01FX33								
International non-proprietary name/INN	Tarlatamab								
Therapeutic indications and ICD code or Orphanet code									
Suggested	Tarlatamab 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.								
Line of therapy	2L+								
Patient population and subgroups	Adult patients with extensive-stage small cell lung cancer (ES-SCLC), who have disease progression on or after first-line treatment with platinum-based chemotherapy.								
Dosage form	Powder for concentrate and solution for solution for infusion								
Quantity of active substance	1 mg and 10 mg								
Final packaging	Packaging of 1 mg: 1 vial of powder for concentrate for solution for infusion and 2 vials of solution (stabiliser). Packaging of 10 mg: 1 vial of powder for concentrate for solution for infusion and 2 vials of solution (stabiliser).								
Posology	Recommended dosing schedule of IMDYLLTRA <table> <tr> <th colspan="2">Dose of IMDYLLTRA</th></tr> <tr> <td>Day 1</td><td>1 mg</td></tr> <tr> <td>Day 8</td><td>10 mg</td></tr> <tr> <td>Day 15 and every 2 weeks thereafter</td><td>10 mg</td></tr> </table>	Dose of IMDYLLTRA		Day 1	1 mg	Day 8	10 mg	Day 15 and every 2 weeks thereafter	10 mg
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Day 1	1 mg								
Day 8	10 mg								
Day 15 and every 2 weeks thereafter	10 mg								
Method of administration	Intravenous use								
Mechanism of action	Tarlatamab is a bispecific T-cell antibody that targets DLL3, a protein expressed in tumors in up to 96% of patients with SCLC. It activates the patient's T-cells to specifically target and eliminate cancer cells expressing DLL3.								

Companion diagnostic	No
Current therapeutics approaches	Chemotherapy
Comparative therapeutic alternatives	Topotecan, CAV (Cyclophosphamide, Doxorubicin, Vincristin), platina-based retreatment
Name of the clinical trial, used in the dossier for marketing authorization application	Study 20210004 (DeLLphi-304)
Clinical trial number	NCT05740566
Clinical trial phase	Phase III
Start date and expected end date of the clinical trial	Start date 31.05.2023 Initial completion date 31.07.2027
Current phase of clinical development of the medicinal product	Phase III
Claimed status of orphan medicinal product (yes/no)	Yes
Registration procedure	Centralized procedure
Expected regulatory approval date (CHMP date and date of regulatory approval)	31.05.2026
Expected date of start of pricing	After decision as part of the JCA procedure

and reimbursement procedure	
Suggested average dose	10 mg
Expected place in the therapeutic pathway, listed in pharmacotherapeutic guidelines	Replacement of certain chemotherapy regimens used in second-line treatment SCLC.
Expected cost (range from-to) for a patient per year or for a patient per episode/cycle if shorter than a year	Potential to reduce costs by slowing disease progression.
Influence on current NHIF expenses	May improve quality of life by slowing disease progression and prolong overall survival.
Influence on patients and patients caregivers	Between 200 and 300 patients per year (upon reaching a peak market share after the fifth year of receiving reimbursement)
PICO	Population (P): 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. Intervention (I): tarlatamab monotherapy Comparatives (C): The most relevant comparator for tarlatamab in patients with ES-SCLC in second-line (2L) is topotecan. Other comparators include CAV and platinum retreatment. Outcomes (O): The primary efficacy endpoint is overall survival (OS). Key secondary efficacy endpoints includes progression-free survival (PFS) based on investigator assessment according to Response Evaluation Criteria in Solid Tumors (RECIST v1.1) and selected patient-reported outcomes. Additional endpoints are overall response rate (ORR) and duration of response (DOR) based on investigator assessment according to RECIST v1.1.