

NSCLC

Clinical Updates from Madrid

LBA5, Amivantamab + Chemotherapy vs Chemotherapy as First-line Treatment in *EGFR* Exon 20 Insertion—Mutated Advanced NSCLC: Study Design of the Randomized Phase 3 Global PAPILLON Study



AUC, area under the curve; BICR, blinded independent central review; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EGFR, epidermal growth factor receptor; NSCLC, non–small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, disease progression; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; TKI, tyrosine kinase inhibitor.

1. Girard N, et al. ESMO 2023. Abstract LBA5. 2. Zhou C, et al. N Engl J Med. 2023. doi:10.1056/NEJMoa2306441.

LBA5, Amivantamab + Chemotherapy vs Chemotherapy as First-line Treatment in *EGFR* Exon 20 Insertion—Mutated Advanced NSCLC: Primary Results of the Randomized Phase 3 Global PAPILLON Study



| | Amivantamab + chemotherapy | Chemotherapy |
|------------|---|--------------|
| ORR | 73% | 47% |
| Median DOR | 9.7 months | 4.4 months |
| Median OS | NE | 24.4 months |
| | HR (95% CI), 0.675 (0.42-1.09) <i>P</i> = .106 | |
| Median DOT | 9.7 months | 6.7 months |

- Grade ≥3 AEs: 75% vs 54%
- Rates of serious AEs (37% vs 31%) and discontinuation of all study agents due to AEs (8% vs 8%) were similar across arms
- Treatment-related discontinuation of amivantamab: 7%

AE, adverse events; BICR, blinded independent central review; DOR, duration of response; DOT, duration of treatment; HR, hazard ratio; NE, not estimable; NSCLC, non–small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

1. Girard N, et al. ESMO 2023. Abstract LBA5. 2. Zhou C, et al. N Engl J Med. 2023. doi:10.1056/NEJMoa2306441.

LBA14, Amivantamab + Lazertinib vs Osimertinib as First-Line Treatment in Patients With *EGFR*-mutated Advanced NSCLC: Study Design of the Phase 3, Global, Randomized, Controlled MARIPOSA Trial



BICR, blinded independent central review; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EGFR, epidermal growth factor receptor; NSCLC, non–small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

Cho BC, et al. ESMO 2023. Abstract LBA14.

LBA14, Amivantamab + Lazertinib vs Osimertinib as First-Line Treatment in Patients With *EGFR*-mutated Advanced NSCLC: Primary Results of the Phase 3, Global, Randomized, Controlled MARIPOSA Trial



BICR, blinded independent central review; HR, hazard ratio; NSCLC, non–small cell lung cancer; PFS, progression-free survival. Cho BC, et al. ESMO 2023. Abstract LBA14. NCT ID: NCT04487080. LBA15, Amivantamab + Chemotherapy ± Lazertinib vs Chemotherapy in *EGFR*-mutated Advanced NSCLC After Progression on Osimertinib: Study Design of MARIPOSA-2, a Phase 3, Global, Randomized, Controlled Trial



AUC, area under the curve; BICR, blinded independent central review; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

1. Passaro A, et al. ESMO 2023. Abstract LBA15. 2. Passaro A, et al. Ann Oncol. 2023;S0923-7534(23)04281-3.

LBA15, Amivantamab + Chemotherapy ± Lazertinib vs Chemotherapy in *EGFR*-mutated Advanced NSCLC After Progression on Osimertinib: PFS in MARIPOSA-2, a Phase 3, Global, Randomized, Controlled Trial



BICR, blinded independent central review; HR, hazard ratio; PFS, progression-free survival. 1. Passaro A, et al. ESMO 2023. Abstract LBA15. 2. Passaro A, et al. *Ann Oncol.* 2023;S0923-7534(23)04281-3.

LBA12, Dato-DXd vs Docetaxel in Previously Treated Advanced/Metastatic NSCLC: Study Design of the Randomized Phase 3 TROPION-Lung01 Study



BICR, blinded independent central review; dato-DXd, datopotamab deruxtecan; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PD-(L)1, programmed cell death protein 1 or its ligand; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization.

Lisberg A, et al. ESMO 2023. Abstract LBA12.

LBA12, Dato-DXd vs Docetaxel in Previously Treated Advanced/Metastatic NSCLC: Results of the Randomized Phase 3 TROPION-Lung01 Study



BICR, blinded independent central review; dato-DXd, datopotamab deruxtecan; DOR, duration of response; HR, hazard ratio; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

Lisberg A, et al. ESMO 2023. Abstract LBA12.

LBA56, KEYNOTE-671 Study of Perioperative Pembrolizumab for Early-Stage NSCLC: Study Design



October 16, 2023: FDA approved pembrolizumab + platinum-based chemotherapy neoadjuvant treatment, with continuation of single-agent pembrolizumab as postsurgical adjuvant treatment for resectable (tumors ≥4 cm or node-positive) NSCLC.

AJCC, American Joint Committee on Cancer; BIPR, blinded independent pathological review; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EFS, event-free survival; FDA, US Food and Drug Administration; IV, intravenous; mPR, major pathological response; NSCLC, non–small cell lung cancer; OS, overall survival; pCR, pathological complete response; PD-L1, programmed cell death protein ligand 1; Q3W, every 3 weeks; R, randomization; TPS, tumor proportion score.

1. Spicer JD, et al. ESMO 2023. Abstract LBA56. 2. Wakelee H, et al. N Engl J Med. 2023;389:491-503. 3. FDA. Oct 16, 2023. https://www.fda.gov.

LBA56, KEYNOTE-671 Study of Perioperative Pembrolizumab for Early-Stage NSCLC: Coprimary Endpoints at IA2



EFS, event-free survival; HR, hazard ratio; IA2, interim analysis 2; NR, not reached; NSCLC, non–small cell lung cancer; OS, overall survival. Spicer JD, et al. ESMO 2023. Abstract LBA56. LBA1, CheckMate 77T: Phase 3 Study Comparing Neoadjuvant Nivolumab + Chemotherapy vs Neoadjuvant Placebo + Chemotherapy Followed by Surgery and Adjuvant Nivolumab or Placebo for Previously Untreated, Resectable Stage II–IIIb NSCLC



Median follow-up: 25.4 months. Database lock date: September 6, 2023.

AJCC, American Joint Committee on Cancer; BIPR, blinded independent pathological review; BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; HR, hazard ratio; mPR, major pathological response; NSCLC, non–small cell lung cancer; OS, overall survival; PBO, placebo; pCR, pathological complete response; PD-L1, programmed cell death protein ligand 1; Q3W, every 3 weeks; Q4W, every 4 weeks; R, randomization.

Cascone T, et al. ESMO 2023. Abstract LBA1. NCT ID: NCT04025879.