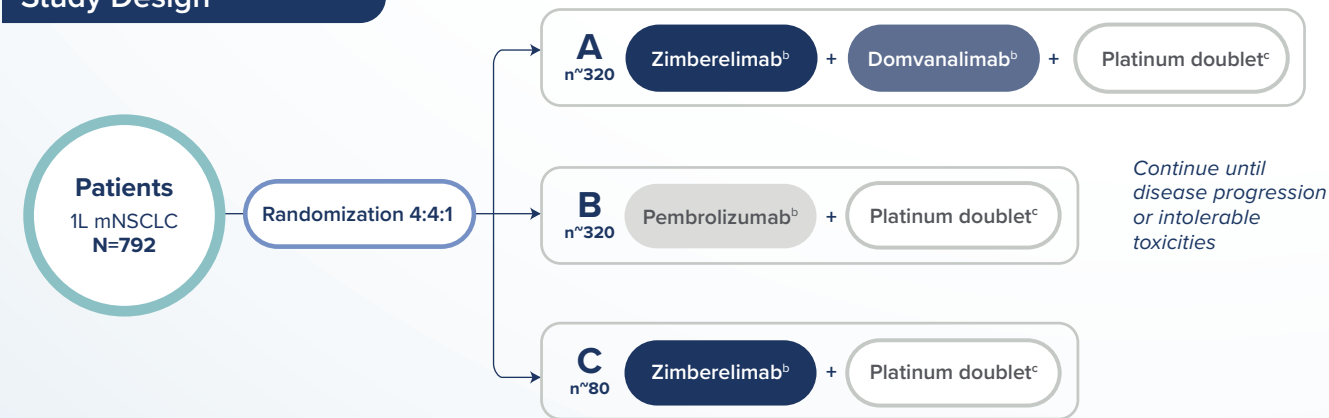


STAR-121: A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy for the 1L Treatment of Patients With Metastatic Non-Small Cell Lung Cancer With No EGFR or ALK Genomic Tumor Aberrations^a

Study Design^{1,2}



^aIn collaboration with Arcus Biosciences. ^bZimberelimab, domvanalimab, and pembrolizumab are given Q3W for a maximum of 35 doses. ^cChoice of chemotherapy is dependent on histology. Participants with non-squamous histology will receive cisplatin 75 mg/m² or carboplatin AUC5 with pemetrexed 500 mg/m² Q3W. Those with squamous histology will receive carboplatin AUC6 Q3W with paclitaxel 200 mg/m² Q3W or nab-paclitaxel 100 mg/m² QW. Note: After the completion of the first 4 cycles, participants with non-squamous histology may continue with maintenance pemetrexed 500 mg/m² IV Q3W until PD or intolerable toxicities. ^dBy BICR using RECIST v1.1.

Key Eligibility Criteria^{1,2}

Key Inclusion Criteria

- Pathologically documented Stage IV NSCLC at the time of enrollment (AJCC 8th edition)
- Documented negative test results for *EGFR* and *ALK* mutations
- No known actionable genomic alterations, including *ROS-1*, *NTRK*, *BRAF*, and *RET*
- Have not received prior systemic treatment for mNSCLC. Adjuvant/neoadjuvant treatment is acceptable if treatment was completed at least 12 months prior to start of study treatment
- Measurable disease per RECIST v1.1 criteria by investigator assessment
- ECOG PS 0-1

Key Exclusion Criteria

- Prior treatment with ICIs
- Known active CNS metastases. Individuals with treated brain metastases may participate, provided they have stable CNS disease for at least 4 weeks prior to enrollment
- History of (noninfectious) pneumonitis/ILD that required steroids or has current pneumonitis/interstitial lung disease

Endpoints^{1,2}

Primary Endpoints

Cohort A vs Cohort B

- PFS^d
- OS

Secondary Endpoints

Cohort A vs Cohort B

- ORR^d
- DOR^d
- Safety
- QoL

1L, first line; AJCC American Joint Committee on Cancer; ALD, anaplastic lymphoma kinase; ALK, anaplastic lymphoma kinase; AUC, area under the curve; BICR, blinded independent central review; BRAF, proto-oncogene B-raf; CNS, central nervous system; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR epidermal growth factor receptor; ICI, immune checkpoint inhibitor; ILD, interstitial lung disease; IV, intravenous; m, metastatic; NSCLC, non-small cell lung cancer; nsq, non-squamous; NTRK, neurotropic tyrosine receptor kinase; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-(L)1, programmed cell death protein (death-ligand) 1 [PD-(L)1]; PFS, progression-free survival; Q3W, every 3 weeks; QoL, quality of life; QW, every week; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; RET, rearranged during transfection (RET)-proto oncogene; ROS-1, ROS proto-oncogene 1; RT, radiation therapy; sq, squamous; TPS, tumor proportion score; v, version; vs, versus.

References

1. Clinicaltrials.gov website. Accessed November 14, 2024. <https://www.clinicaltrials.gov/study/NCT05502237>
2. Data on file. Gilead Sciences, Inc.; 2022.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available.