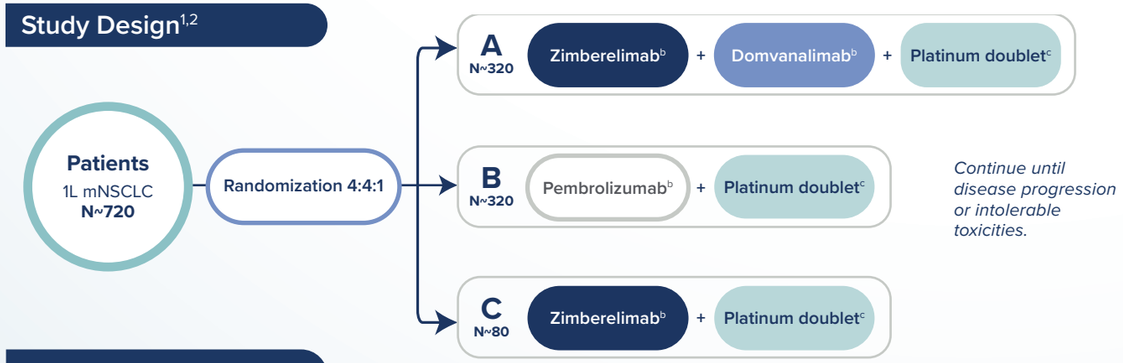
ClinicalTrials.gov Identifier: NCT05502237

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]



Continue until disease progression or intolerable toxicities.

Enrollment

Study Population

1L metastatic NSCLC

- Metastatic NSCLC with no actionable mutations
- No prior systemic treatment for metastatic NSCLC
- PD-L1 all comers
- ECOG PS 0-1
- No interstitial lung disease
- No untreated brain metastases

[a]In collaboration with Arcus Biosciences. [b]Zimberelimab, domvanalmab, and pembrolizumab are given Q3W for a maximum of 35 doses. [c]Choice of chemotherapy is dependent on histology. Participants with non-squamous histology will receive cisplatin 75 mg/m^2 or carboplatin AUC5 with pemetrexed 500 mg/m^2 Q3W. Those with squamous histology will receive carboplatin AUC6 Q3W with paclitaxel 200 mg/m^2 Q3W or nab-paclitaxel 100 mg/m^2 QW. Note: After the completion of the first 4 cycles, participants with non-squamous histology may continue with maintenance pemetrexed 500 mg/m^2 IV Q3W until PD or intolerable toxicities. [d]By BICR using RECIST v1.1.

STAR-121

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 *ROS1, NTRK, BRAF*, and *RET*
- Have not received prior systemic treatment for metastatic NSCLC. 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

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

Endpoints[1,2]

Primary Endpoint

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; 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; NSCLC, non-small cell lung cancer; NSq, nonsquamous; NTRK, neurotropic tyrosine receptor kinase; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-(L)1, programmed cell death (ligand) 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; ROS1, ROS proto-oncogene 1; RT, radiation therapy; Sq, squamous; TPS, tumor proportion score.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://www.clinicaltrials.gov/ct2/show/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. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05502237

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