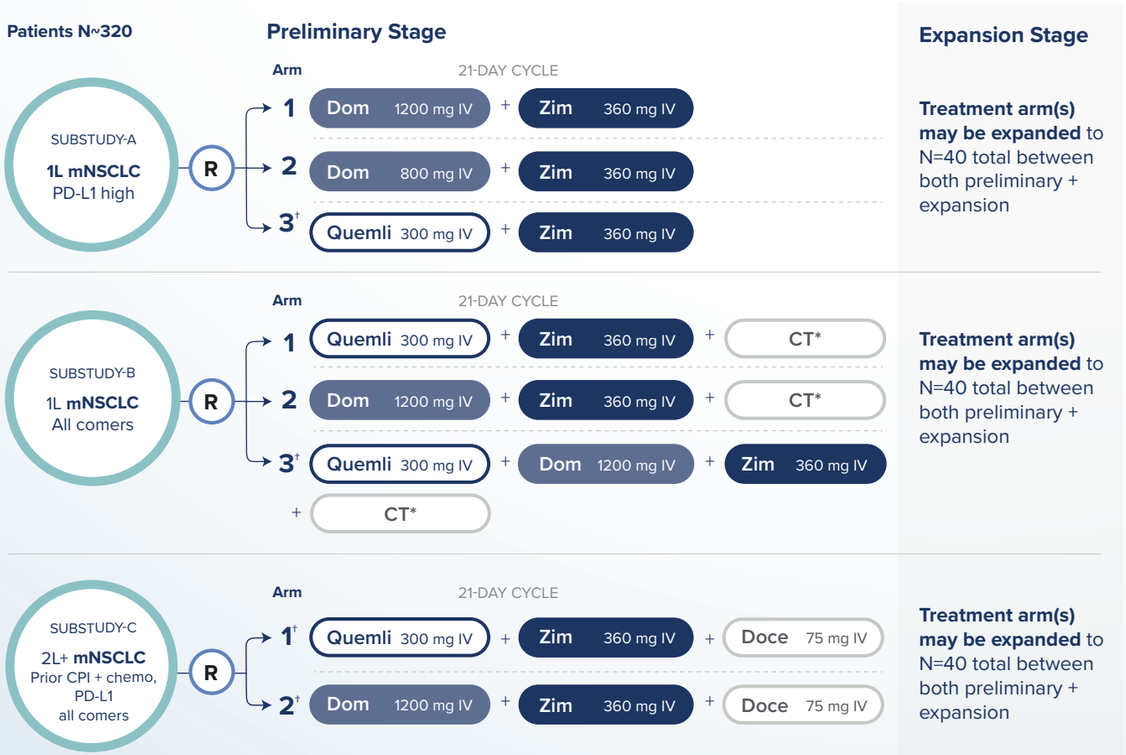
ClinicalTrials.gov Identifier: NCT05676931

EDGE-Lung: A Phase 2, Open-Label, Platform Study, to Evaluate Immunotherapy-Based Combinations in Participants With Advanced NSCLC[a]

Study Design[1-3]



*Platinum doublet chemotherapy. †Not yet recruiting.

Stratification[1-3,b]

Substudy A
- Histology: squamous vs non-squamous

Substudy B
- PD-L1 ≥50% vs <50%
- Histology: squamous vs non-squamous

Substudy C
- Histology: squamous vs non-squamous

Key Eligibility Criteria[1-3,b]

Key Inclusion Criteria
- Histologically confirmed, documented diagnosis of Stage IV mNSCLC
- Age ≥18 years
- ECOG PS of 0 or 1
- Adequate organ and marrow function
- ≥1 measurable disease according to RECIST v1.1
- Participants must be willing to provide adequate tumor tissue
- For patients with brain metastases: asymptomatic for ≥4 weeks. Carcinomatous meningitis is excluded

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[a]In collaboration with Arcus Biosciences. [b]Other protocol defined Inclusion/Exclusion criteria may apply.

1L, first line; 2L+, second line or greater; CPI, checkpoint inhibitor; CT, chemotherapy; Doce, docetaxel; Dom, domvanalimab; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IP, investigational product; m, metastatic; NSCLC, non-small cell lung cancer; PD-L1, programmed death-ligand 1; Quemli, quemliclustat; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; v, version; Zim, Zimberelimab.

The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05676931

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EDGE-Lung

Key Eligibility Criteria[1-3,b] (cont'd)

Key Exclusion Criteria

- Presence of *ALK* or *EGFR* mutation. Patients with unknown status and non-squamous histology must be tested at prescreening. (Not required for patients with squamous histology)
- Presence of any other tumor genomic aberrations or driver mutations (eg, *ROS-1, BRAF, NTRK*) for which a targeted therapy is approved by local health authority and available
- Underlying medical conditions that, in the Investigator's or Sponsor's opinion, will make the administration of IP(s) hazardous
- Use of any live vaccines against infectious diseases within 28 days of first dose of IP(s)
- Concurrent chronic medical condition requiring the use of supra-physiologic doses of corticosteroids (>10 mg/day of oral prednisone or equivalent) or immunosuppressive medications (absorbable topical corticosteroids are not excluded)
- Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial
- Any active autoimmune disease or a documented history of autoimmune disease or syndrome that required systemic treatment in the past 2 years (ie, with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs), except for vitiligo or resolved childhood asthma/atopy
- Receipt of radiotherapy within 2 weeks of C1D1 or radiotherapy that is >30 Gy[c] within 6 months of C1D1
- Mixed SCLC and NSCLC histology

Substudy Inclusion Criteria[1-3,b]

Substudy A

- Treatment naïve in the metastatic setting
- Locally-assessed PD-L1 high expression (TPS ≥50% by PharmDx 22C3 or 28-8 pharmDx (Dako) or TC ≥50% by SP263)

Substudy B

- Treatment naïve in the metastatic setting
- Locally-assessed PD-L1 expression (by PharmDx 22C3, 28-8 pharmDx (Dako) or SP263)
- CrCl ≥45 mL/min (60 mL/min for participants receiving cisplatin)

Substudy C

- PD or recurrence after platinum-based chemotherapy and anti-PD-(L)1 therapy, given concurrently or sequentially
- No PD for at least 12 weeks after initiation of prior anti-PD-(L)1 therapy
- Documented radiographic PD on or after the most recent regimen for mNSCLC
- No more than 2 prior lines of systemic therapy for metastatic disease

Substudy Exclusion Criteria[1-3,b]

Substudy A and B

- Prior treatment with any anti-PD-1, anti-PD-L1, or any other antibody targeting an immune checkpoint

Substudy C

- Prior lung cancer treatment with docetaxel, anti-TIGIT, or anti-adenosine therapies

Endpoints[1-3,b]

Primary Endpoints

- ORR
- Safety and tolerability

Secondary Endpoints

- OS
- PFS
- DCR
- DOR
- PK
- ADAs

[c]One gray (Gy) is the international system of units (SI) equivalent of 100 rads, which is equal to an absorbed dose of 1 Joule/kilogram.

ADA, antidrug-antibody; ALK, anaplastic lymphoma kinase; C1D1, cycle 1 day 1; CrCl, creatinine clearance; DCR, disease control rate; DOR, duration of response; EGFR, epidermal growth factor receptor; IP, investigational product; ITIM, immunoreceptor tyrosinebased inhibitory motif; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; ORR, objective response rate; ROS-1, ROS proto-oncogene 1; SCLC, small cell lung cancer; TC, tumor cell expression; TIGIT, T cell immunoreceptor with Ig and ITIM domains; TPS, tumor proportion score.

References

1. Clinicaltrials.gov website. Accessed May 3, 2024. https://clinicaltrials.gov/ct2/show/NCT05676931
2. Data on file. Gilead Sciences, Inc.; 2022.
3. Johnson M, et al. WLCL 2023. TiP P2.08-07.

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