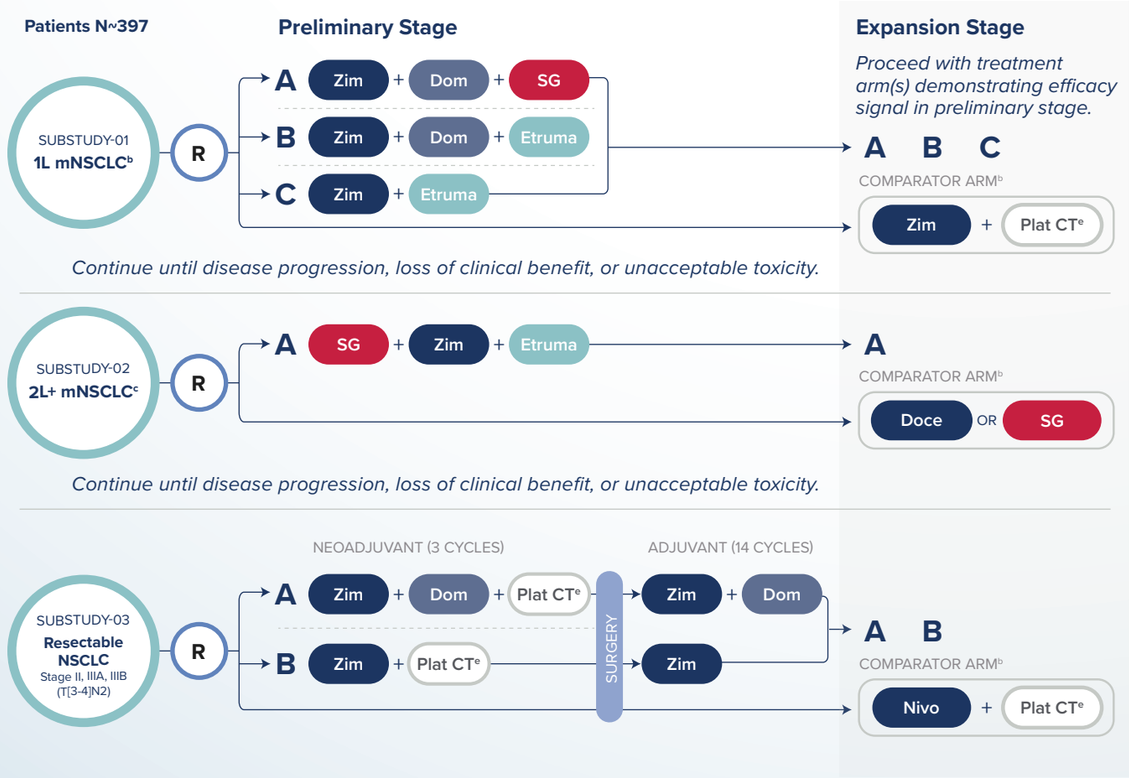
ClinicalTrials.gov Identifier: NCT05633667

VELOCITY-Lung: A Phase 2 Platform Study Evaluating the Safety and Efficacy of Novel Treatment Combinations in Patients With Lung Cancer[a]

Study Design[1,2]



Stratification[1,2]

Substudy-01: 1L NSCLC

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

Substudy-02: 2L+ NSCLC

- Histology: squamous vs non-squamous
- Prior therapy for actionable genomic alteration (yes or no)

Substudy-03: Resectable NSCLC

- PD-L1 by SP263 (≥50% vs <50% tumor staining)
- Stage (II vs III)

Enrollment[1,2]

Substudy-01: 1L NSCLC

- Metastatic NSCLC without actionable mutation
- No prior systemic treatment for metastatic NSCLC
- PD-L1 all-comers
- ECOG PS 0-1
- No untreated or unstable brain metastases

Substudy-02: 2L+ NSCLC

- Metastatic NSCLC
- Disease progression after platinum-based chemotherapy and anti-PD-1 or anti-PD-L1 antibody
- PD-L1 all-comers
- ECOG PS 0-1
- No untreated or unstable brain metastases

Substudy-03: Resectable NSCLC

- Resectable Stage II, IIIA, IIIB (T[3-4]N2) NSCLC
- EGFR/ALK wild-type
- PD-L1 all-comers

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[a]In collaboration with Arcus Biosciences.[b]Patients with mNSCLC who are treatment naive with no actionable mutations. [c]Patients with mNSCLC who have no actionable mutations who have progressed post-chemotherapy and PD-1/PD-L1 therapy. Patients with actionable genomic alternations must have received targeted treatment with at least 1 approved TKI. [d]Choice of comparator based on the patient characteristics and treatment arms in expansion stage. [e]Choice of chemotherapy is dependent on histology.

1L, first-line; 2L, second-line; Doce, docetaxel; Dom, domvanalimab; ECOG PS, Eastern Cooperative Oncology Group performance status; Etruma, etrumadenant; Nivo, nivolumab; NSCLC, non-small cell lung cancer; PD-L1, programmed death ligand 1; R, randomization; SG, sacituzumab govitecan; TKI, tyrosine kinase inhibitor; 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.

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Key Eligibility Criteria[1,2,f]

Key Inclusion Criteria - All substudies

- Age ≥18 years
- Histologically or cytologically documented NSCLC
- No known actionable genomic alterations for which approved therapies are available
- ECOG PS score of 0 or 1
- Measurable disease as per RECIST 1.1 criteria
- Adequate hematologic and end-organ function
- Individuals of childbearing potential who engage in heterosexual intercourse must agree to use specified method(s) of contraception

Key Exclusion Criteria - All substudies

- Mixed SCLC and NSCLC histology
- Active second malignancy
- Active autoimmune disease
- History of or current non-infectious pneumonitis/ interstitial lung disease
- Active serious infection within 4 weeks prior to study treatment

Substudy Criteria[1,2,f]

Substudy-01 Inclusion Criteria

All Experimental Arms

- Stage IV NSCLC
- For individuals with nonsquamous histology: EGFR or ALK alteration negative
- PD-L1 status by central confirmation
- No prior systemic treatment for metastatic NSCLC

Substudy-02 Inclusion Criteria

All Experimental Arms

- Stage IV NSCLC
- In individuals with nonsquamous histology and actionable EGFR, ALK, or other known genomic alterations must have received treatment with at least 1 targeted therapy to the appropriate genomic alteration

Substudy-01 and -02 Exclusion Criteria

- Known active CNS metastases and/or carcinomatous meningitis
- Received previous anticancer therapy within 4 weeks prior to enrollment

ALK, anaplastic lymphoma kinase; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; NSCLC, non small cell lung cancer; PD-L1, programmed death ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer.

Substudy Criteria[1,2,f] (cont'd)

Substudy-03 Inclusion Criteria

All Experimental Arms

- Previously untreated individuals with resectable (Stage II, IIIA, IIIB (T[3-4]N2) NSCLC (per AJCC Edition 8)
- Planned surgery must comprise of lobectomy, sleeve lobectomy, or bi-lobectomy
- PD-L1 status by central confirmation
- For individuals with nonsquamous histology: EGFR or ALK alteration negative

Substudy-03 Exclusion Criteria

All Experimental Arms

- NSCLC previously treated with systemic therapy or radiotherapy
- Received prior treatment with any anti-PD-(L)-1 or other immune CPIs

Endpoints[1,2]

Primary Endpoint

- **Substudy-01 and -02:** ORR, investigator assessed per RECIST v1.1
- **Substudy-03:** pCR Rate

Secondary Endpoints

- **All substudies:**
  - OS
  - Incidence of AEs and laboratory abnormalities
- **Substudy-01 and -02:**
  - PFS per RECIST v1.1
  - DOR per RECIST v1.1
- **Substudy-03:**
  - EFS
  - MPR

[f]Other protocol-defined inclusion/exclusion criteria may apply.[1]

AEs, adverse events; AJCC, American Joint Committee on Cancer; ALK, anaplastic lymphoma kinase; CPI, checkpoint inhibitor; DOR, duration of response; EFS, event-free survival; EGFR, epidermal growth factor receptor; MPR, major pathological response; ORR, objective response rate; OS, overall survival; pCR, Complete Pathological Response; PFS, progression free survival; RECIST, Response Evaluation Criteria in Solid Tumors.

References

1. Clinicaltrials.gov website. Accessed February 6, 2024. https://clinicaltrials.gov/ct2/show/NCT05633667
2. Data on file. Gilead Sciences, Inc.; 2022.

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