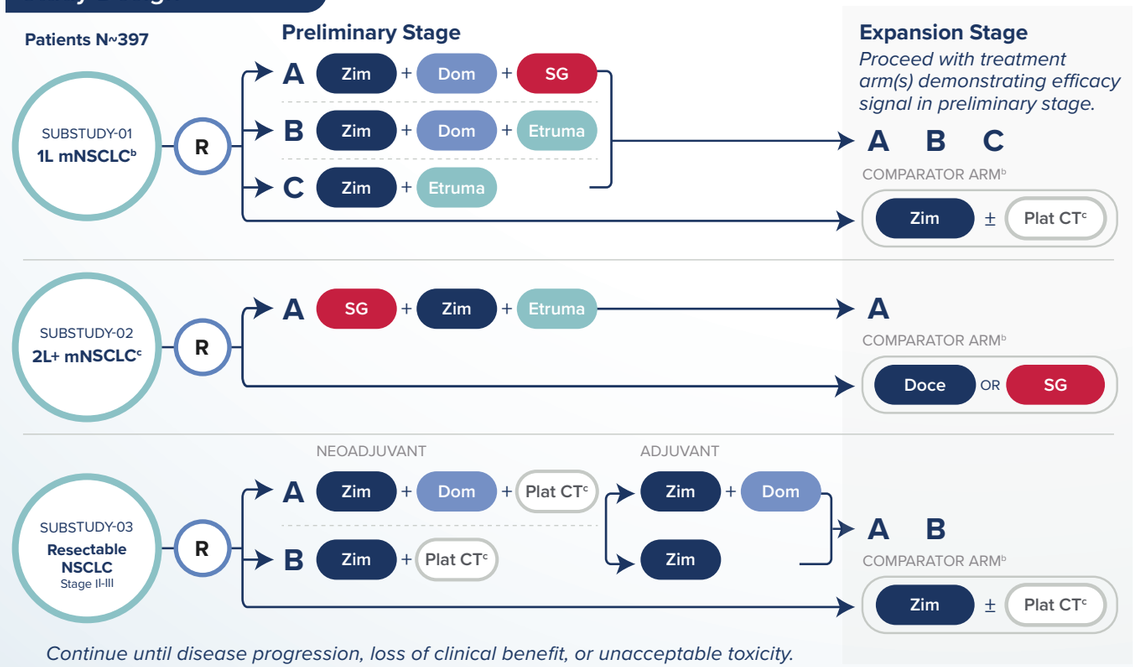
ClinicalTrials.gov Identifier: NCT05633667

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]



Continue until disease progression, loss of clinical benefit, or unacceptable toxicity.

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

1L, first-line; 2L, second-line; NSCLC, non-small cell lung cancer; R, randomization; Dom, domvanalimab; Etruma, etrumadenant; SG, sacituzumab govitecan; Zim, zimberelimab.

Enrollment

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

Key Eligibility Criteria[1,2,f]

Key Inclusion Criteria

- Age ≥18 years
- Histologically or cytologically documented NSCLC with evidence of stage IV disease
- No known actionable genomic alterations for which approved therapies are available
- No prior systemic treatment for metastatic NSCLC
- 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

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

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CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-(L)1, programmed death (ligand) 1; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer.

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: NCT05633667

US-UNBP-2430 11/23

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

Substudy-01 Inclusion Criteria

All Experimental Arms

- For individuals with nonsquamous histology: *EGFR* or *ALK* alteration negative
- No known genomic alterations in *ROS1, NTRK, BRAF, RET* mutations, or other actionable genomic alterations
  - Testing is not required if status is unknown
- Have determination of PD-L1 status by central testing prior to enrollment
- Have not received prior systemic treatment for mNSCLC
  - Patients who received adjuvant or neoadjuvant therapy are eligible if the therapy was completed at least 12 months prior to the start of study intervention

Substudy-02 Inclusion Criteria

All Experimental Arms

- In individuals with nonsquamous histology, individuals with *EGFR, ALK,* or any other known actionable genomic alterations must have received treatment with at least 1 approved TKI appropriate to the genomic alteration
- Progression or disease recurrence after platinum-based chemotherapy with anti-PD-1 or anti-PD-L1 antibody OR sequential treatment (in any order)

Substudy-03 Inclusion Criteria

All Experimental Arms

- Previously untreated individuals with resectable (Stage II, IIIA, IIIB (T[3-4]N2) NSCLC (per American Joint Committee on Cancer (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

Endpoints

Primary Endpoint

- ORR

Secondary Endpoints

- PFS
- DOR
- Incidence of AEs and laboratory abnormalities
- OS

AEs, adverse events; ALK, anaplastic lymphoma kinase; BRAF, proto-oncogene B-raf; DOR, duration of response; EGFR, epidermal growth factor receptor; m, metastatic; NTRK, neurotrophic tyrosine receptor kinase; ORR, objective response rate; OS, overall survival; PFS, progression free survival; RET, rearranged during transfection (RET)-proto oncogene; ROS1, ROS proto-oncogene; TKI, tyrosine kinase inhibitor.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT05633667
2. Data on file. Gilead Sciences, Inc.; 2022.

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