Duravelo-4 Clinical Trial

(BT8009-202) NCT06933329

NECTIN4-amplified advanced or metastatic non-small cell lung cancer (NSCLC)

A phase 2 study of Nectin-4–targeting Bicycle® Drug Conjugate zelenectide pevedotin (BT8009) in patients with previously treated *NECTIN4*-amplified advanced or metastatic non-small cell lung cancer (NSCLC)

Not yet recruiting

PRIMARY ANALYSIS

Previously treated squamous or nonsquamous *NECTIN4*-amplified NSCLC

N≈73

COHORT A
Nonsquamous NSCLC
zelenectide pevedotin
D1/D8 of a 21-day cycle

COHORT B
Squamous NSCLC
zelenectide pevedotin
D1/D8 of a 21-day cycle

Contact **clinicalstudies@bicycletx.com** to enroll patients and learn more.

See eligibility criteria on reverse side.

Primary endpoint:
ORR

D=day; ORR=objective response rate.

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Are your patients eligible?

At the most recent data cutoff from Duravelo-1, zelenectide pevedotin demonstrated a tolerable safety profile and preliminary antitumor activity in *NECTIN4*-amplified lung cancer.[1-3]

Key eligibility criteria

Inclusion

- Histologically or cytologically confirmed advanced or metastatic NSCLC
- Confirmed *NECTIN4* gene amplification
- No more than 3 prior lines of systemic therapy in the advanced/metastatic setting
- Participants with no known actionable genomic alterations must have received both platinum-based therapy and immunotherapy (sequentially or in combination)
- Participants with known actionable genomic alterations are eligible provided they have received or are not candidates for standard targeted therapy in the advanced/metastatic setting
- Adequate archival or fresh tumor tissue comprised of advanced or metastatic NSCLC
- Measurable disease as defined by RECIST v1.1
- Life expectancy ≥12 weeks
- ECOG PS ≤1

COHORT A

- Histologically or cytologically confirmed nonsquamous NSCLC

COHORT B

- Histologically or cytologically confirmed squamous NSCLC

Exclusion

- Mixed small cell lung cancer (SCLC) and NSCLC histology
- Active or untreated CNS metastases
- Prior treatment with any MMAE-based therapy
- Prior treatment with any systemic anticancer therapy within 28 days (or 5 half-lives)
- Ongoing Grade ≥2 toxicity associated with prior treatment (with the exception of well-controlled immuno-oncology related endocrine disorders on supportive or replacement therapy, and alopecia)
- Uncontrolled pleural or pericardial effusion or ascites requiring recurrent draining procedures
- Active ILD or pneumonitis requiring ongoing treatment or any prior history of ILD or noninfectious pneumonitis requiring high-dose glucocorticoids

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Product candidates are investigational only and are not approved medicines.

CNS=central nervous system; ECOG PS=Eastern Cooperative Oncology Group Performance Status; ILD=interstitial lung disease; MMAE=monomethyl auristatin E; RECIST=Response Evaluation Criteria in Solid Tumors.

References: 1. Baldini C, et al. Presented at: 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL. Abstract 498. **2.** Bader J, et al. Presented at: 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL. Abstract 3088. **3.** Verlingue L, et al. Presented at 2025 European Lung Cancer Congress; March 26-29, 2025; Paris, France. Abstract 96P.

Additional protocol-defined inclusion/exclusion criteria apply.

Bicycle