Duravelo-3 Clinical Trial

(BT8009-201) NCT06840483

NECTIN4-amplified advanced breast cancer

A phase 2 study of Nectin-4–targeting Bicycle® Drug Conjugate zelenectide pevedotin (BT8009) in patients with *NECTIN4*-amplified advanced breast cancer

Actively recruiting

PRIMARY ANALYSIS

***NECTIN4*-amplified TNBC or HR+/HER2- breast cancer**

N≈66

COHORT A
HR+/HER2– BC
zelenectide pevedotin
D1/D8 of a 21-day cycle

COHORT B
TNBC
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

BC=breast cancer; D=day; HER2-=human epithelial growth factor receptor 2 negative; HR+=hormone receptor-positive; ORR=objective response rate; TNBC=triple negative breast cancer.

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Are your patients eligible?

Key eligibility criteria

Inclusion

- Unresectable or metastatic TNBC or HR+/HER2- breast cancer
- Confirmed *NECTIN4* gene amplification
- Measurable disease as defined by RECIST v1.1
- Life expectancy ≥12 weeks
- ECOG PS ≤2

COHORT A

- Confirmed HR+/HER2- endocrine resistant/refractory BC
- ≤3 prior lines of non-endocrine therapy for advanced disease

COHORT B

- Confirmed TNBC, including ER-low positive BC[a]
- 1 to 3 prior lines of systemic therapy for advanced disease

Exclusion

- Previously tested HER2+ (IHC 3+ or ISH+)
- 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)

Additional protocol-defined inclusion/exclusion criteria apply.

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

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Product candidates are investigational only and are not approved medicines.

[a]1-10% of cells expressing hormonal receptors by IHC.

BC=breast cancer; CNS=central nervous system; ECOG PS=Eastern Cooperative Oncology Group performance status; ER=estrogen receptor; HER2-=human epidermal growth factor 2-negative; HR+=hormone receptor-positive; IHC 3+=immunohistochemistry 3-positive; ISH+=in situ hybridization-positive; MMAE=monomethyl auristatin E; RECIST=Response Evaluation Criteria in Solid Tumors; TNBC=triple-negative breast cancer.

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.** Klümper N, et al. Presented at San Antonio Breast Cancer Symposium; December 10-13, 2024; San Antonio, TX. Poster P4-10-21.

Bicycle