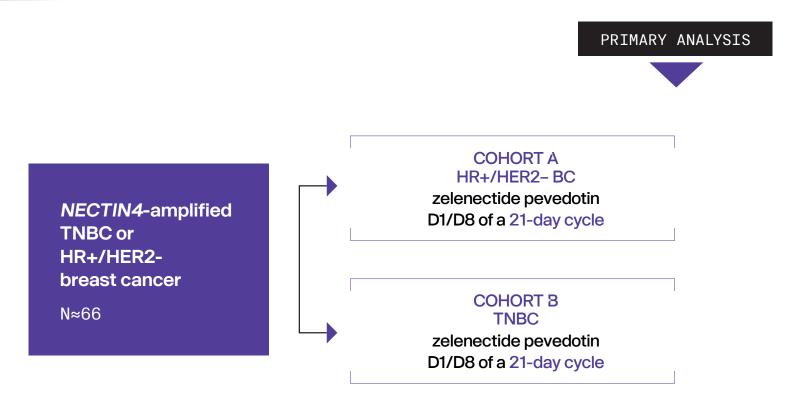


A phase 2 study of Nectin-4-targeting Bicycle® Drug Conjugate zelenectide pevedotin (BT8009) in patients with *NECTIN4*-amplified advanced breast cancer

Actively recruiting



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



See eligibility criteria on reverse side.

Primary endpoint: ORR



Are your patients eligible?

Key eligibility criteria

Inclusion

- Unresectable or metastatic TNBC or HR+/HER2- breast cancer
- (V) Confirmed NECTIN4 gene amplification
- (V) Measurable disease as defined by RECIST v1.1
- Life expectancy ≥12 weeks
- COG 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°
- 1 to 3 prior lines of systemic therapy for advanced disease

Exclusion

- $\stackrel{\textstyle (\times)}{}$ Previously tested HER2+ (IHC 3+ or ISH+)
- (\times) 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)

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.

^a1-10% 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.

