Zanidatamab (ZW25) in Combination with Evorpacept (ALX148) in Advanced Human Epidermal Growth Factor Receptor 2 (HER2)-expressing Cancers, Including Breast Cancer: A Phase 1b, Multicenter, Open-Label, and Cohort-Expansion Study (ZWI-ZW25-204)

Zara A. Huriwit1, Jorge Chaves2, Adam Brukwy3, Alberto J. Montero1, Bruno Fang1, Kay Yeung1,2, Manish R. Patel1, Ritesh Parajuli1, Adam Omidpanah1, Elaina Gartner1, Abraham Fong1,4, Sophia Randolph1,2, Funda Memic-Bernstam1,3
1University of California Los Angeles Comprehensive Cancer Center, Los Angeles, CA, USA; 2Rochester Medical Specialties, Rochester, MN, USA; 3University of Pittsburgh Abandoned Center, Pittsburgh, PA, US; 4Kaiser-Permanente-Cancer Center, Seattle, WA, US; 5Scripps Cancer Center, La Jolla, CA, US; 6University of California, Irvine, Orange, CA, US; 7Fimmcyt, Inc., Vancouver, BC, Canada; 8ALX Oncology Ltd, South San Francisco, CA, US; 9The University of Texas MD Anderson Cancer Center, Houston, TX, US

BACKGROUND AND RATIONALE

- Zanidatamab is designed with multiple mechanisms of action, including immune clearance, durable antitumor activity against HER2-expressing tumors, and ADCC.
- In combination with evorpacept, zanidatamab has shown potential to augment antitumor activity across HER2-expressing tumors.
- Zanidatamab features a unique biparatopic design that allows for simultaneous targeting of HER2.
- Zanidatamab is approved for the treatment of patients with HER2-amplified biliary tract cancer.

Evolpacept (ALX148) is a novel anti-CD47 antibody that blocks the CD47 signal and prevents recognition by macrophages, allowing cancer cells to avoid phagocytosis.

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REFERENCES


STUDY OBJECTIVES AND DESIGN

Part 1: Safety Evaluation (3+3 Dose Escalation Design) (Cohorts 1 and 2 only)

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- Cohort 1: HER2-positive breast cancer (Cohort 1)
- Cohort 2: HER2-low breast cancer (Cohort 2)

Part 2: Expansion Cohorts

- Cohort 3: HER2-expressing non-breast cancer patients (Cohort 3)

Eligibility

- Locally advanced (stage III) or metastatic HER2-expressing cancer at any site:
  - breast cancer
  - HER2-low breast cancer
  - HER2-low non-breast cancer
  - HER2-positive non-breast cancer

Study Status

The study is currently open for enrollment at 8 sites in the US

Acknowledgements

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