

Avenzo Therapeutics Announces First Patient Dosed in Combination Cohort Evaluating CDK4 Selective Inhibitor (AVZO-023) with CDK2 Selective Inhibitor (AVZO-021) In Ongoing Phase 1/2 ORION-1 Study

SAN DIEGO, Calif. – May 28, 2026 – [Avenzo Therapeutics, Inc.](#) (“Avenzo”), a clinical-stage biotechnology company developing next-generation oncology therapies, today announced that the first patient has been dosed in the combination cohort evaluating AVZO-023, its potentially differentiated cyclin-dependent kinase 4 (CDK4) selective inhibitor, in combination with AVZO-021, its potentially differentiated cyclin-dependent kinase 2 (CDK2) selective inhibitor, with fulvestrant in patients with advanced or metastatic hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) breast cancer in the ongoing Phase 1 portion of the ORION-1 Phase 1/2 clinical study.

The Phase 1/2 first-in-human, open-label ORION-1 clinical study is designed to assess the safety, tolerability, and preliminary clinical activity of AVZO-023 with endocrine therapy as well as the combination of AVZO-023 and AVZO-021 with endocrine therapy. The combination cohort will evaluate AVZO-023 and AVZO-021 with fulvestrant in patients with HR+/HER2- advanced or metastatic breast cancer. AVZO-021 is currently being studied in a separate Phase 1/2 clinical study in HR+/HER2- advanced or metastatic breast cancer and other advanced solid tumors, and the company plans to present updated safety and efficacy results from the Phase 1 portion of the ongoing study at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

“We are proud to have dosed the first patient in this combination cohort,” said Mohammad Hirmand, M.D., Co-founder and Chief Medical Officer of Avenzo Therapeutics. “We believe this novel combination of AVZO-023 and AVZO-021 with fulvestrant may provide a differentiated treatment approach, and we look forward to continuing to evaluate its potential to meaningfully improve outcomes for patients with HR+/HER2- breast cancer.”

About Avenzo Therapeutics

Avenzo Therapeutics is a clinical-stage biotechnology company focused on developing next-generation oncology therapies for patients. The company’s pipeline includes potentially differentiated small molecules and antibody-drug conjugates (ADCs). Avenzo’s small molecule inhibitors, AVZO-021 and AVZO-023, are novel, highly potent and selective inhibitors of CDK2 and CDK4, respectively, which are key enzymes involved in cell cycle regulation. AVZO-021 is being studied in a Phase 1/2 study for the treatment of advanced solid tumors and in combinations in HR+/HER2- metastatic breast cancer. AVZO-021 and AVZO-023 are being studied in the ORION-1 Phase 1/2 study for the treatment of HR+/HER2- metastatic breast cancer, where AVZO-023 is administered in combination

with endocrine therapy, with or without AVZO-021. Avenzo's first ADC drug candidate, AVZO-1418, is a potentially differentiated EGFR/HER3 bispecific ADC that is being studied in the AVENTINE-1 Phase 1/2 study for the treatment of advanced solid tumors. Avenzo's second ADC drug candidate, AVZO-103, is a potentially differentiated Nectin4/TROP2 bispecific ADC that is being studied in the BEACON-1 Phase 1/2 study for the treatment of advanced solid tumors. Avenzo is headquartered in San Diego, California. For more information, visit us at www.avenzotx.com or on [LinkedIn](#).

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