NEWS RELEASE

AVENZO THERAPEUTICS ANNOUNCES FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR AVZO-023 (ARTS-023), A POTENTIAL BEST-IN-CLASS, NOVEL CDK4 SELECTIVE INHIBITOR

2025-05-21

Avenzo has exercised its exclusive option for global (excluding Greater China) development, manufacturing, and commercialization rights for AVZO-023

Phase 1/2 first-in-human clinical study planned for third quarter this year

SAN DIEGO, Calif. – May 21, 2025 – Avenzo Therapeutics, Inc. ("Avenzo"), a clinical-stage biotechnology company developing next-generation oncology therapies, today announced clearance by the U.S. Food and Drug Administration (FDA) of its investigational new drug application (IND) for AVZO-023 (formerly ARTS-023), a potential best-in-class, novel cyclin-dependent kinase 4 (CDK4) selective inhibitor. Avenzo has also exercised its exclusive option for AVZO-023 from Allorion Therapeutics Inc., securing global (excluding Greater China) development, manufacturing, and commercialization rights.

Under the IND, the company plans to initiate a Phase 1/2 first-in-human, open-label clinical study in the third quarter of this year. The Phase 1 portion will assess the safety, tolerability, and preliminary clinical activity of AVZO-023 as a single agent and in combination therapy with endocrine therapy and with AVZO-021, Avenzo's potential best-in-class CDK2 inhibitor, in patients with advanced or metastatic hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) breast cancer and select other advanced solid tumors. AVZO-021 is currently being studied in HR+/HER2- metastatic breast cancer and other advanced solid tumors.

“The clearance of our IND for AVZO-023 represents an important milestone on our journey to transform cancer treatment,” said Mohammad Hirmand, M.D., Co-founder and Chief Medical Officer of Avenzo Therapeutics. “We believe AVZO-023 has the potential to be a best-in-class oncology therapy for patients with HR+/HER2- breast cancer and we look forward to initiating a Phase 1/2 clinical trial, and to studying the potential of AVZO-023 in combination with our potential best-in-class CDK2 selective inhibitor, AVZO-021.”

Preclinical data for AVZO-023 were presented for the first time at the American Association for Cancer Research (AACR) Annual Conference in April 2025 and highlighted its sub-nanomolar potency against CDK4 while sparing other CDKs with high selectivity over CDK6, a key driver of hematologic toxicity. In addition, AVZO-023 demonstrated efficacy in *in vivo* xenograft models, both as a single agent and in combination with AVZO-021.

About Avenzo Therapeutics

Avenzo Therapeutics is a clinical-stage biotechnology company focused on developing next-generation oncology therapies for patients. The company’s lead drug candidate, AVZO-021, is a novel, highly potent and selective inhibitor of CDK2, a key enzyme involved in cell cycle regulation. AVZO-021 is being studied in a Phase 1 study in the U.S. and Australia for the treatment of advanced solid tumors and in combinations in HR+/HER2-negative metastatic breast cancer. Avenzo is headquartered in San Diego, California. For more information, visit us at **www.avenzotx.com** or on **LinkedIn**.

Avenzo Therapeutics Contact:
Carla Taub
Media Relations
ctaub@avenzotx.com