NEWS RELEASE

AVENZO THERAPEUTICS ANNOUNCES FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR AVZO-103, A POTENTIAL BEST-IN-CLASS NECTIN4/TROP2 BISPECIFIC ANTIBODY-DRUG CONJUGATE

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Avenzo has exercised its exclusive option for global (excluding Greater China) development, manufacturing, and commercialization rights for AVZO-103

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

SAN DIEGO, Calif. – Sept. 2, 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-103 (formerly VAC-103), a potential best-in-class Nectin4/TROP2 bispecific antibody-drug conjugate (ADC). Avenzo has also exercised its exclusive option for AVZO-103 from VelaVigo, 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 later this year. The Phase 1 portion will assess the safety, tolerability, and preliminary clinical activity of AVZO-103 as a single agent and in combination therapy in patients with advanced solid tumors.

"The clearance of our IND for AVZO-103 marks our third IND clearance this year, highlighting the productivity and dedication of our R&D team," said Mohammad Hirmand, M.D., Co-founder and Chief Medical Officer of Avenzo

Therapeutics. “This bispecific ADC is designed to simultaneously target Nectin4 and TROP2 to potentially enhance tumor cell killing while sparing normal tissue. We look forward to studying its potential to address significant unmet needs for patients with cancers that co-express these targets, including urothelial 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 potential best-in-class 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, the company’s lead drug candidate, 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- metastatic breast cancer. AVZO-023 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. Avenzo’s first ADC drug candidate, AVZO-1418, is a potential best-in-class, EGFR/HER3 bispecific ADC that is being studied in a 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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