NEWS RELEASE

AVENZO THERAPEUTICS ANNOUNCES FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR AVZO-1418, A POTENTIAL BEST-IN-CLASS, NOVEL EGFR/HER3 BISPECIFIC ANTIBODY-DRUG CONJUGATE

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

SAN DIEGO, Calif. – May 22, 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-1418 (DB-1418), a potential best-in-class, novel EGFR/HER3 bispecific antibody-drug conjugate (ADC).

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-1418 as a single agent and in combination therapy in patients with advanced solid tumors.

"The clearance of our IND for AVZO-1418 is a significant achievement for Avenzo as this is our second IND in 3 weeks to receive clearance and our first ADC program to advance into the clinic," said Mohammad Hirmand, M.D., Co-founder and Chief Medical Officer of Avenzo Therapeutics. "We believe AVZO-1418 has a differentiated profile with the potential to benefit patients across various solid tumors. We look forward to initiating our Phase 1/2 study later this year and working closely with our partner, Duality Biotherapeutics."

Preclinical data for AVZO-1418 were presented for the first time at the American Association for Cancer Research

(AACR) Annual Conference in April 2025 and highlighted AVZO-1418's novel design and additive binding affinity in EGFR and HER3 co-expressing tumor cells. In addition, AVZO-1418 demonstrated efficacy in *in vivo* xenograft models across multiple tumor types, including in an EGFR TKI-resistant non-small cell lung cancer model.

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. The company's second drug candidate, AVZO-023, is a novel, highly potent and selective inhibitor of CDK4. The company plans to initiate a Phase 1/2 clinical study for AVZO-023 in the third quarter of 2025 in patients
with advanced or metastatic HR+/HER2- breast cancer and other 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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