NEWS RELEASE

AVENZO THERAPEUTICS GRANTED FAST TRACK DESIGNATION FOR AVZO-1418, A POTENTIAL BEST-IN-CLASS EGFR/HER3 BISPECIFIC ANTIBODY-DRUG CONJUGATE, FOR THE TREATMENT OF PATIENTS WITH EGFR-MUTATED TKI-PRETREATED NSCLC

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SAN DIEGO, Calif. – Nov. 10, 2025 – Avenzo Therapeutics, Inc. ("Avenzo"), a clinical-stage biotechnology company developing next-generation oncology therapies, today announced the U.S. Food and Drug Administration (FDA) granted Fast Track designation to AVZO-1418 (DB-1418), a potential best-in-class EGFR/HER3 bispecific antibody-drug conjugate (BsADC).

The designation was granted for the treatment of patients with unresectable, locally advanced, or metastatic non-small cell lung cancer (NSCLC) with an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation, whose disease has progressed on or after therapy with an EGFR tyrosine kinase inhibitor (TKI).

"We are excited to receive this Fast Track designation from the FDA, underscoring the promise of AVZO-1418, especially for patients with EGFR-Mutated TKI-Pretreated NSCLC," said Mohammad Hirmand, M.D., Co-founder and Chief Medical Officer of Avenzo Therapeutics. "This designation has the potential to help expedite the development of AVZO-1418, which we continue to rapidly advance in Phase 1."

AVZO-1418 is currently being studied in a Phase 1/2 first-in-human, open-label clinical study designed to 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.

About Fast Track Designation

Fast Track is a FDA process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- Rolling Review of a Biologic License Application or New Drug Application by the FDA

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 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's second ADC drug candidate, AVZO-103, is a potential best-in-class, Nectin4/TROP2 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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