Aminex Therapeutics Announces Multiple Sites Activated for Phase 1b/2 Clinical Trial of Novel Investigational Cancer Treatment AMXT 1501 and DFMO in Patients with solid tumors including primarily Breast Cancer and Melanoma

- Novel approach attacks production of polyamines that tumors require to proliferate and suppress the immune system

SEATTLE, WA — February 4, 2026 — Aminex Therapeutics, Inc., a private clinical-stage biotechnology company focused on developing novel therapies for rare and difficult-to-treat cancers, today announced the initiation of & first patient treated in a Phase 1b/2 clinical trial of AMXT 1501 in combination with difluoromethylornithine (DFMO) in patients with breast cancer or metastatic melanoma.

“Initiating enrollment in this study is an important milestone for Aminex and for patients facing advanced cancers with limited treatment options,” said Mark Burns, PhD, Chief Scientific Officer and President of Aminex. “This trial builds on our foundation of pre- and early clinical data demonstrating the potential of AMXT 1501 plus DFMO to block the polyamine metabolism—a pathway that drives tumor growth and suppresses immune responses. We are advancing this program, in collaboration with leading adult oncology investigators and pediatric oncologists, targeting eight aggressive solid tumor types.”

The multicenter, open-label trial (NCT07287917) will evaluate the safety, tolerability and preliminary efficacy of oral AMXT 1501 in combination with oral DFMO in addition to standard of care therapy in metastatic melanoma and in pre- and post-menopausal women with ER+ HER2- breast cancer who have progressed on prior therapies. The study will evaluate safety in dose escalation and efficacy in dose expansion cohorts.

In addition to this trial, Aminex is partnering with The Beat Childhood Cancer Consortium at Penn State College of Medicine on a randomized Phase 1/2 clinical trial of AMXT 1501 plus DFMO in pediatric patients with neuroblastoma, diffuse intrinsic pontine glioma, atypical teratoid rhabdoid tumor, embryonal tumor with multilayer rosettes, ewing sarcoma, and osteosarcoma. (NCT06465199) Aminex also recently announced the receipt of Orphan Drug Designation from the FDA for AMXT 1501 plus DFMO for the treatment of patients with neuroblastoma.

About AMXT 1501 and DFMO

AMXT 1501 is a novel polyamine transport inhibitor designed to block the uptake of polyamines, which are essential for tumor growth and survival. DFMO is an established inhibitor of polyamine biosynthesis. Together, the combination aims to comprehensively inhibit polyamine metabolism and tumor growth.

About Aminex Therapeutics, Inc.

Aminex Therapeutics, Inc. is a private clinical-stage biotechnology company focused on the development of AMXT 1501, a novel small molecule combination immunotherapy for the treatment of cancer. For more information, visit www.aminextx.com.

# # #

(for press only)

Media Contact:
Julie Rathbun
Rathbun Communications
Julie@rathbuncomm.com
206-769-9219