Aminex Therapeutics Receives Second FDA Orphan Drug Designation for AMXT 1501 for Malignant Glioma Including DIPG - a Highly Aggressive Childhood Brain Cancer

- *Designation Underscores the Significant Unmet Medical Need as AMXT 1501 Advances in Two Active National Clinical Trials — Including a Pediatric Study Now Enrolling Children with DIPG*

SEATTLE, WA — March 12, 2026 — Aminex Therapeutics, Inc., a clinical-stage biotechnology company focused on developing a novel metabolic-targeted therapy to treat adult and pediatric cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to AMXT 1501 in combination with difluoromethylornithine (DFMO) for the treatment of malignant glioma, including diffuse intrinsic pontine glioma (DIPG). This is the company's second Orphan Drug Designation, following the ODD granted in October 2025 for neuroblastoma.

"This second Orphan Drug Designation is a powerful validation of AMXT 1501's potential to make a meaningful difference for patients facing some of the most devastating cancers," said Mark Burns, PhD, Chief Scientific Officer and President of Aminex Therapeutics. "DIPG is heartbreaking — children diagnosed with this brain tumor have virtually no effective treatment options and very little time. We are committed to changing that."

DIPG is an aggressive brainstem tumor that primarily strikes children aged 5 to 10, with a median survival of less than 12 months from diagnosis. There is currently no cure.

For Families of Children with DIPG and Other High-Risk Cancers: A Trial Is Now Enrolling

The Beat Childhood Cancer Research Consortium at Penn State College of Medicine, in partnership with Aminex, is actively enrolling patients in a national Phase 1/2 clinical trial of AMXT 1501 plus DFMO in pediatric patients with DIPG, neuroblastoma, sarcomas and other high-risk childhood cancers. The trial is planned to open at 50 clinics nationwide and enroll patients. For more information, visit ClinicalTrials.gov (NCT06465199) to learn more.

AMXT 1501 is also being evaluated in adults with solid tumors including breast cancer and metastatic melanoma in an active Phase 1b/2 multicenter trial (NCT07287917.)

The FDA's Orphan Drug Designation provides Aminex with development incentives including tax credits, fee waivers, and seven years of market exclusivity upon potential approval.

About Aminex Therapeutics, Inc. Aminex Therapeutics, Inc. is a clinical-stage biotechnology company developing AMXT 1501, a novel small molecule polyamine transport inhibitor, in combination with DFMO, a polyamine synthesis inhibitor. For more information, visit www.aminextx.com.

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