Tern Therapeutics Receives US FDA Fast Track Designation for TTX-381 Gene Therapy for the Treatment of the Ocular Manifestations of CLN2 Disease

- *Designation to expedite development of lead program TTX-381.*
- *First-in-human clinical trial to evaluate TTX-381 is active and recruiting patients.*

WASHINGTON, DC, April 8, 2025 —Tern Therapeutics, LLC ("Tern"), a biotechnology company developing transformative one-time gene therapies for rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to TTX-381. TTX-381 is a novel one-time gene therapy product being developed for the treatment of the ocular manifestations of CLN2 disease, a form of Batten disease.

"We are pleased the FDA has granted Fast Track designation to TTX-381, recognizing its potential to transform the lives of patients with CLN2 disease," said Alex Bailey, Ph.D., Chief Executive Officer of Tern. "This marks an important milestone for Tern and reinforces the promise of TTX-381 to address the rapid, relentless loss of vision caused by CLN2 disease. With this designation, we look forward to working closely with the FDA to accelerate development and bring this much-needed therapy to patients as quickly as possible."

The FDA's Fast Track program is designed to help drugs reach patients sooner by expediting the development and regulatory review of therapies that address serious conditions with unmet medical needs. This designation facilitates increased interactions with the FDA during the clinical development process, as well as ensures eligibility for rolling review, priority review, and accelerated approval. TTX-381 previously received rare pediatric disease and orphan drug designations from the FDA.

About TTX-381

TTX-381 is an investigational one-time AAV gene therapy designed to deliver a working copy of the *TPP1* gene directly to the retina, potentially providing a durable source of TPP1 to maintain the health of the retina and address vision loss in people with CLN2 disease. Vision loss in children with CLN2 disease rapidly progresses to blindness; there is currently no available treatment for the ocular manifestations of CLN2 disease. The first-in-human clinical trial to evaluate TTX-381 is active and recruiting patients. Learn more at clinicaltrials.gov (NCT05791864).

ABOUT TERN THERAPEUTICS

TERN THERAPEUTICS is a privately held biotechnology company founded in 2023 with a new vision for speeding the development of transformative, one-time gene therapy medicines for rare diseases. Guided by a team of leading physicians, scientists, and business leaders and in collaboration with patient communities, we are driven to deliver transformative treatments with urgency to those living around the world with rare diseases. For more information about Tern, please visit WWW.TERNTX.COM.

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