EMBARGO: 8 January 2026 0700 ET (12pm GMT)

VectorY Therapeutics Receives FDA Fast Track Designation for VTx-002, a First-in-Class Vectorized Antibody Targeting Underlying Disease Biology in ALS

~ Designation enables an enhanced development path for VTx-002 and underscores its disease-modifying potential in ALS, a universally fatal disease with no cure ~
~ Milestone follows recent IND clearance and supports continued advancement of VTx-002 toward the planned PIONEER-ALS Phase 1/2 clinical study ~

Amsterdam, The Netherlands, and Boston, MA — [January 8, 2026] — VectorY Therapeutics, a leader in vectorized antibody therapies for neurodegenerative diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for VTx-002, a first-in-class vectorized antibody targeting TDP-43 pathology in amyotrophic lateral sclerosis (ALS).

"ALS is a devastating and relentlessly progressive disease with profound unmet medical need, and patients urgently need new therapeutic options," said Jim Scibetta, chief executive officer of VectorY. "The FDA's decision to grant Fast Track designation to VTx-002 underscores the seriousness of ALS and the importance of advancing new investigational approaches. This designation enables closer and more frequent interaction with the FDA as we prepare to advance VTx-002 into the upcoming PIONEER-ALS Phase 1/2 clinical study, with the goal of moving as efficiently and responsibly as possible on behalf of patients."

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of Fast Track Designation is to get important new drugs to patients earlier. A therapy that receives Fast Track designation may be eligible for more frequent meetings and communications with the FDA and may also be eligible for Priority Review in the future.

VTx-002 targets TDP-43 pathology, which drives up to 97 percent of ALS cases. In December 2025, the Company announced that the FDA cleared its Investigational New Drug (IND) application for VTx-002 for the treatment of ALS and concurrently announced plans to initiate PIONEER-ALS, a Phase 1/2 clinical study designed to evaluate the safety, tolerability, and pharmacodynamic activity of VTx-002 in people

living with ALS. VectorY intends to enroll its first patient in the PIONEER-ALS study in early 2026.

About ALS

ALS is a universally fatal neurodegenerative disease with no cure and only limited symptomatic treatment options. In the United States, more than 5,000 new cases of ALS are diagnosed each year, and more than 30,000 people are currently living with the disease. Median survival is 2–3 years after a diagnosis, and someone is either diagnosed with or dies from ALS every 90 minutes. The disease has an incidence comparable to major indications such as multiple sclerosis, yet far lower prevalence reflecting a persistent disease burden and urgent unmet medical need.

About VectorY Therapeutics

VectorY Therapeutics is dedicated to changing the trajectory of neurodegenerative diseases by developing precision-targeted, durable therapies that have the potential to arrest and ultimately reverse disease progression. With deep expertise in neurobiology, antibody engineering, and AAV-based delivery, VectorY is building a pipeline that includes VTx-002 targeting TDP-43 in ALS, VTx-001 targeting oxidized phospholipids in ALS, VTx-003 targeting mutant HTT and TDP-43 in Huntington's disease, VTx-005 targeting phosphorylated tau in Alzheimer's disease, and VTx-004 targeting TDP-43 in frontotemporal dementia (FTD).

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