HOPE Neuron Therapeutx

MILESTONES & CLINICAL DEVELOPMENT TIMELINE

2024–2025 – Preclinical & IRB Activation

- ALS mouse model data completed
- Device safety & feasibility validated in preclinical setting
- Ongoing IP expansion (U.S., Japan, Canada, China)
- Institutional Review Board (IRB) submission – Barrow GWF ALS Clinic
- Additional transgenic model testing (MS, PD)

2025–2026 – Early Clinical Trials

- IRB clearance and Phase 0/1 dosing study (ALS patients)
- Biomarker validation and patient safety tracking
- Optimize device design and manufacturing pathway
- Begin FDA dialogue on Breakthrough Device designation

2026–2027 – Regulatory & Commercial Expansion

- Initiate multicenter ALS trial (Mayo, Banner Health, others)
- Submit FDA IDE or early marketing authorization request
- Begin preliminary discussions with EU/Canada regulators
- Strategic partner engagement (distribution & licensing)
- LONG-TERM PIPELINE VISION. Target expansion to MS, Parkinson's, Alzheimer's

Scale point-of-care device distribution
Explore platform licensing for autoimmune and inflammatory indications

We are entering the most critical phase — transitioning from proof of concept to clinical translation. This raise supports the final steps to human trials and FDA strategy.