

# NeuroGenesis Awarded Grant from National MS Society's Fast Forward Program to Advance Cell Therapy & Phase IIb Trial

*NeuroGenesis has been awarded a grant from the National MS Society to advance its NG01 cell therapy and launch its Phase IIb trial for secondary progressive MS.*

ROCHESTER, NY, UNITED STATES, May 8, 2025 /EINPresswire.com/ -- [NeuroGenesis](#), a clinical-

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*Tal Gilat, CEO and Co-Founder*

stage biotech company, is dedicated to pioneering cell therapy solutions for neurodegenerative diseases such as Multiple Sclerosis (MS) and Amyotrophic Lateral Sclerosis (ALS). The company is excited to announce its selection for a prestigious grant from the [National MS Society's](#) Fast Forward program, which supports commercial organizations advancing innovative therapies for MS. This funding will fuel NeuroGenesis' global Phase IIb clinical trial, focusing on new treatments for MS patients.

Preceded by four successful clinical trials in Europe and Israel, the upcoming global Phase IIb trial led by Professor Flavia Nelson, Whigham-Berger Chair in Neuroimmunology

and Director of the Comprehensive MS Center at the University of Miami, will further validate the efficacy of NeuroGenesis' [NG01](#) cellular therapy platform for patients with Secondary Progressive MS.

CEO and Co-Founder Tal Gilat expressed gratitude for the grant, stating, “We are honored to receive this support from the National MS Society. NG01 has shown promising results in reversing disease progression, promoting remyelination, and improving patients' lives. We appreciate the Society's confidence in our work and are excited to launch this trial in the US.”

NeuroGenesis is pioneering a biomarker-driven approach to assess treatment success in its Phase IIb trial. By measuring cerebrospinal fluid (CSF) and serum biomarkers such as Glial Fibrillary Acidic Protein (GFAP) and Neurofilament light polypeptides (NfL), the study will evaluate NG01's impact on reducing these indicators, correlating biomarker changes with improved neurological function. Neurological disability will be measured through standard assessments, including the Expanded Disability Status Scale (EDSS), Timed 25-Foot Walk, and advanced MRI

metrics detecting remyelination.

Integrating high-throughput proteomics and biomarker technology, the trial aims to enhance treatment precision by identifying individuals most likely to respond to NG01. This approach will be incorporated into future Phase III trials, optimizing patient selection, improving patient outcomes, and accelerating FDA approval.

Dr. Nir Netzer, COO of NeuroGenesis, emphasized the significance of the grant, stating, "This funding helps refine our patient selection methodology, improving predictive capabilities. With cutting-edge proteomics, we aim to increase trial success rates and ensure NG01 reaches patients who need it most."

"There is a critical unmet need for therapies that focus on repairing myelin and restoring function to people with secondary progressive multiple sclerosis," says Walter Kostich, PhD, Associate Vice President, Translational Research at the National MS Society. "We are pleased to provide funding to NeuroGenesis to support their Phase IIb clinical trial and hope these studies will support it as a safe and effective treatment option for this population."

#### About the National Multiple Sclerosis Society

Founded in 1946, the National MS Society leads the global effort to cure MS and improve the lives of those affected. The organization funds research, drives advocacy efforts, and provides essential services to the MS community. Learn more at [nationalmssociety.org](https://nationalmssociety.org).

#### About NG01 Cellular Therapy

NG01 is a unique population of autologous bone marrow-derived stem cells engineered to secrete high levels of remyelinating and neurotrophic factors directly at injury sites in the central nervous system. Administered via cerebrospinal fluid, NG01 targets damaged brain and spinal cord regions, stimulating robust remyelination and repair through neurotrophic factor secretion. The therapy also exerts significant neuroprotective and anti-inflammatory effects. NG01 has undergone four successful clinical trials since 2010, demonstrating improved EDSS scores, reduced brain lesions, and enhanced mobility. The Phase I and II trials validated NG01's safety and efficacy, setting the foundation for its upcoming Phase IIb study.

#### Phase IIb Clinical Trial

The National MS Society's funding supports NeuroGenesis' double-blind, placebo-controlled trial for SPMS patients. The study's primary focus includes improvements in walking speed and patient tolerance to different injection volumes compared to placebo. Secondary endpoints cover confirmed disability worsening (CDW), advanced MRI-based remyelination assessments, quality-of-life evaluations, biomarker analysis, and cognitive testing. Over nine months, patients will receive four intrathecal NG01 injections, with results anticipated in early 2028.

## About NeuroGenesis

NeuroGenesis is a privately held clinical-stage company developing cell-based therapies for neurodegenerative diseases. Its cellular therapy platform delivers high concentrations of neuroprotective, neurotrophic, and anti-inflammatory proteins directly to damaged brain regions.

NG01, the company's lead product, has received FDA clearance for a global Phase IIb placebo-controlled trial for SPMS patients. To date, NG01 has been administered to over 100 patients in clinical trials and compassionate use settings.

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