

NeuroGenesis Announces Positive Phase 2 Extension Study Results of NG01 Cell Therapy in Progressive Multiple Sclerosis

Study shows NG01 improved mobility, cognition, and quality of life, marking a step forward in treatment for progressive multiple sclerosis.



Innovative therapies targeting the root causes of progressive multiple sclerosis and ALS.

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EINPresswire.com/ -- NeuroGenesis

today announced new positive results

from the Phase 2 extension study of NG01, an innovative autologous stem cell therapy for people living with progressive [multiple sclerosis](#).

The study, conducted at the Hadassah University Hospital Multiple Sclerosis Center in Jerusalem,



Our mission is to deliver therapies that transform outcomes for patients. NG01 is the first proof point, and our platform aims to reshape treatment for neurodegenerative diseases worldwide."

Tal Gilat, CEO of NeuroGenesis

involved patients who completed the Phase 2 Placebo-Controlled trial (which was published in the journal "BRAIN" in 2020). These patients were treated with repeated injections of NG01 and followed for more than a year. The findings reveal that the effect of this treatment goes beyond stabilizing the disease, inducing potential neuroprotective and neuro-regenerative effects in the central nervous system.

Progressive multiple sclerosis is one of the most challenging conditions to treat, leading to steady and irreversible disability. Few therapies to date have shown an

ability to alter the biological drivers of progression. NG01 demonstrated measurable proof that it can reduce damage inside the brain and spinal cord, while also improving day-to-day functioning.

In the study (published recently in the journal of Neuroimmunology), serum neurofilament light chain, a marker of neuronal injury, which has been used as a surrogate endpoint to prove efficacy in various neurodegenerative diseases and to support accelerated approval of new

therapies for such diseases, declined by a mean of 33 percent over one year. Glial fibrillary acidic protein, a key marker of neuroinflammation, was also strongly downregulated, with levels dropping from an average of 165.7 pg/mL at baseline to 127.2 pg/mL after one year.

Most importantly, both biomarkers were consistent across nearly all patients, indicating beneficial effects of the treatment on both the neurodegenerative and neuroinflammatory processes. Such (double) effect has not been observed in any of the current MS therapies. Neurological functional improvements mirrored these biological changes.

Patients walked faster, with the median time to complete a 25-foot walk improving by 17 percent after the first injection and remaining better at one year. Cognitive performance improved by more than three points on the Symbol Digit Modalities Test, a change widely recognized as clinically meaningful. Quality-of-life scores also improved, with patients reporting gains in mental health and reductions in fatigue. Safety was favorable, with no serious adverse events observed; minor effects such as headache or backache resolved within 48 hours.

Tal Gilat, CEO of NeuroGenesis, said: "Our mission has always been to move beyond incremental improvements and deliver therapies that fundamentally change outcomes for patients and families. NG01 is our first proof point, but the platform extends far beyond MS. We believe stem cell innovation can reshape the treatment of neurodegenerative diseases worldwide, and NeuroGenesis is committed to leading that transformation.

The combination of robust biomarker evidence and consistent functional gains tells a powerful story. NG01 is not only slowing the biological processes behind progressive MS but is also enabling patients to walk faster, think more clearly, and feel better in their daily lives. This alignment between laboratory data and clinical experience is rarely seen in progressive MS and marks NG01 as a potential first-in-class therapy.

For the Multiple Sclerosis community, the results provide a concrete basis for optimism, grounded in rigorous science. For physicians, the study offers objective data that reinforces what patients are experiencing in practice. And for investors and partners, the strong biomarker signals and functional benefits help de-risk the development path and highlight NG01's potential in a multi-billion-dollar market.

Professor Dimitrios Karussis, MD, PhD, Hadassah University Hospital, the author of the study stated: "In progressive MS, we rarely see both biological markers and clinical function improving in tandem. The fact that patients not only showed reductions in key markers of nerve damage and inflammation but also experienced meaningful gains in walking speed, cognition, and quality of life, is significant. These results point to NG01 as a therapy with the potential to truly change the treatment landscape for progressive MS."

NeuroGenesis is committed to advancing NG01 on the strength of these findings and sees the therapy as the cornerstone of a broader platform for neurodegenerative diseases. With both

biological validation and meaningful patient outcomes now demonstrated, the company is poised to take the next steps in bringing this therapy to the people who need it most.

NeuroGenesis is advancing its mission of delivering breakthrough therapies that protect and repair the nervous system. As the company continues to build on the strength of NG01 and its broader platform, it welcomes investors and strategic investment partnerships that align with its vision. Such collaborations will help accelerate development, extend the reach of its innovations, and bring meaningful new treatments to patients and families affected by neurodegenerative disease.

About NeuroGenesis

NeuroGenesis is a clinical-stage biotechnology company developing next-generation autologous stem cell therapies for serious neurodegenerative diseases. Its lead candidate, NG01, is being evaluated in multiple sclerosis and amyotrophic lateral sclerosis to deliver therapies that both protect and repair the nervous system. NeuroGenesis is headquartered in Rochester, NY.

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