FDA Grants NeuroGenesis Bio RMAT Designation for NG01 for Treatment of Secondary Progressive Multiple Sclerosis

RMAT designation is based on promising Phase 2 clinical data demonstrating NG01's potential to reduce disability and improve function in patients with PMS.

LAFAYETTE, CA, UNITED STATES, March 18, 2026 /EINPresswire.com/ -- NeuroGenesis Bio Announces U.S. FDA Grants Regenerative Medicine Advanced Therapy (RMAT) Designation for NG01 for the Treatment of Secondary Progressive Multiple Sclerosis

Designation is based on promising Phase 2 clinical data demonstrating NG01's potential to reduce disability, improve function, and decrease disease biomarkers in patients with Progressive MS.

NeuroGenesis Bio Inc., a clinical-stage biotechnology company advancing cell therapies for neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to its lead candidate, NG01, for the treatment of Secondary Progressive Multiple Sclerosis (SPMS).

RMAT designation was granted based on clinical evidence from a Phase 2, double-blind, placebo-controlled, randomized study, demonstrating that intrathecal administration of NG01 may slow disease progression, reduce disability, and improve function (walking and hand dexterity) in Progressive MS patients. NG01 treatment was also associated with a reduction of key biomarkers of neurodegeneration (NfL and GFAP).

"Receiving RMAT designation is a significant milestone for NG01 and, most importantly, for the MS patient community," said Tal Gilat, CEO, NeuroGenesis Bio. "Secondary Progressive MS is a debilitating condition with a profound unmet need for therapies that go beyond merely slowing decline. This designation validates our substantial human data collected from over 120 patients and allows us to work closely with the FDA to accelerate delivery of NG01 to patients who desperately need therapies that can promote repair and improve function".

Established under the 21st Century Cures Act, the RMAT designation expedites the development and review of promising regenerative medicine therapies targeting serious or life-threatening conditions with unmet medical needs. The designation provides intensive FDA guidance, eligibility for priority review, potential for accelerated approval based on surrogate or

intermediate endpoints, and post-approval flexibility.

Dr. Andrew Goodman, Professor of Neurology at the University of Rochester, NY, and world-renowned key opinion leader in MS care, added: “The clinical data for NG01 demonstrates comprehensive benefit across multiple outcomes. By bypassing the blood-brain barrier via intrathecal delivery, we are seeing not only stabilization and reduction in critical neurodegenerative biomarkers, but also functional improvement. This RMAT designation recognizes the strong scientific foundation of this novel approach.”

About NG01

NG01 is an innovative, investigational, remyelinating autologous cell therapy, administered directly into the cerebrospinal fluid, that bypasses the blood-brain barrier and homes to brain lesions. Unlike approved standard-of-care therapies that focus on broad immune suppression, NG01 employs a multi-domain mechanism that secretes neurotrophic factors specifically at sites of nerve damage to reduce inflammation and promote active myelin repair. NG01 has been administered to over 120 patients.

In a Phase 2 randomized, double-blind, placebo-controlled trial of 48 Progressive MS patients (Petrou et al., Brain 2020), NG01 showed the following preliminary findings:

- Improvement in Disability: Clinically meaningful reduction in the Expanded Disability Status Scale (EDSS) vs. placebo (-0.5 points, $p<0.0001$).

- Improved function: Improvements in walking speed (Timed 25-Foot Walk, $p<0.01$) and fine motor skills (9-Hole Peg Test, $p< p<0.02$) in treated patients compared to placebo.

- Reduction in Disease-related Biomarkers: Reduced levels of serum NfL (nerve damage, $p<0.001$) and GFAP (neuroinflammation, $p<0.001$, extension study).

- Reduction in Disease Progression Risk: 84% reduction in relative risk of treatment failure vs. placebo (6.7% vs. 41.9%, $p<0.001$).

To date, NG01 is being studied under an FDA-cleared IND application in a global Phase 2b placebo-controlled study in SPMS.

About NeuroGenesis Bio

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

The company's social mission is to provide transformative therapies for people with

neurodegenerative diseases. The company is currently raising capital from a combination of institutional and private investors in support of this mission.

Forward Looking Statements

This press release contains forward-looking statements regarding the potential therapeutic benefits of NG01, the implications of the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation, and the future development of NG01. These statements are subject to risks and uncertainties inherent in clinical research, regulatory review, and product development that could cause actual results to differ materially from those expressed or implied. NeuroGenesis Bio undertakes no obligation to update forward-looking statements except as required by law.

Investor Relations
Neurogenesis Bio Inc.
info@neurogenesis-cell.com
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