

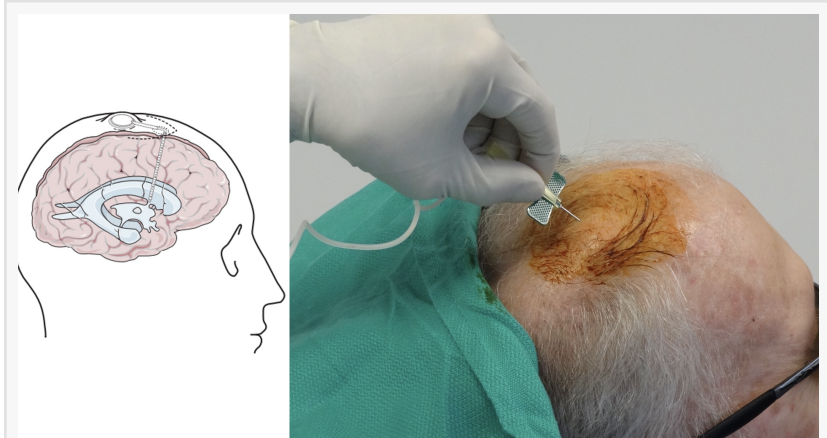
RBI Granted 'Fast Track' Designation by FDA, Validating Its Direct-to-Brain Stem Cell Therapy for Alzheimer's Disease

Designation Follows Encouraging Phase I Results and FDA Clearance of a Multi-Center, Double-Blind, Placebo-Controlled Phase II Trial

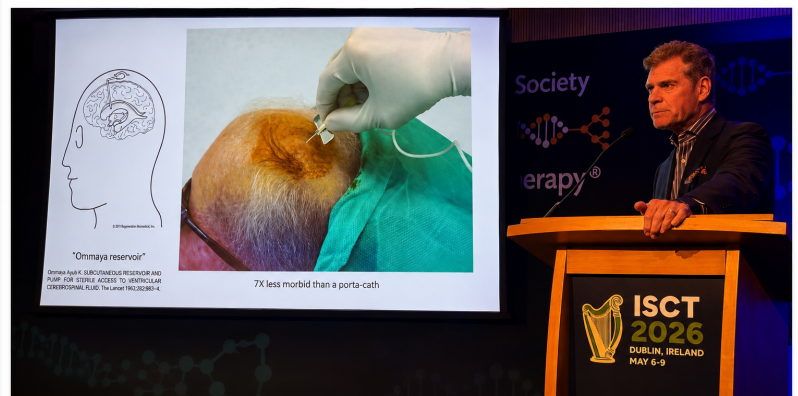
NEWPORT BEACH, CA, UNITED STATES, June 15, 2026 /EINPresswire.com/ -- [Regeneration Biomedical, Inc. \(RBI\)](#), a clinical-stage biotechnology company developing direct-to-brain autologous stem cell therapies for neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted "Fast Track" designation to the company's investigational stem cell therapy for Alzheimer's disease.

The designation follows encouraging results from RBI's FDA-cleared Phase I clinical trial in six patients with mild-to-moderate Alzheimer's disease. Patients received a single intracerebroventricular (ICV) administration of RBI's autologous [Wnt-activated adipose-derived stem cells, delivered directly into the brain](#) to bypass the blood-brain barrier.

The Phase I study demonstrated an excellent safety profile, with no treatment-related serious adverse events, together with sustained improvements in multiple cerebrospinal fluid (CSF) biomarkers



Regeneration Biomedical is the first to inject stem cells directly into the brain for Alzheimer's disease. A Phase 2 trial is pending.



Caption: Dr. Christopher Duma presenting first-in-mankind data from Regeneration Biomedical, Inc.'s Phase I clinical trial of RB-ADSC, a Wnt-activated autologous adipose-derived stem cell therapy delivered directly into the brain via an Ommaya reservoir. The study demonstrated significant and sustained improvements in CSF amyloid beta, p-Tau, histones, and cognitive measures following a single intracerebroventricular injection in patients with mild-to-moderate Alzheimer's disease. Findings were presented May 6-9, 2026 at the International Society for Cell & Gene Therapy Annual Meeting (ISCT 2026) in Dublin, Ireland.

Dr. Christopher Duma presenting first-in-mankind Phase I clinical data for Regeneration Biomedical's direct-to-brain Wnt-activated stem cell platform at the International Society for Cell & Gene Therapy (ISCT) 2026 Annual Meeting in Dublin, Ireland.

associated with Alzheimer's disease. Patients exhibited normalization or improvement of amyloid beta, phosphorylated tau, total tau, and histone biomarkers, along with exploratory cognitive improvements following a single administration.

The FDA's "Fast Track" program is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs. The designation provides opportunities for more frequent interactions with the FDA and the potential for accelerated development and review pathways.

The FDA's decision to grant "Fast Track" designation follows encouraging Phase I results in six patients and underscores the potential of RBI's novel direct-to-brain approach. To the company's knowledge, RBI is among the first organizations to receive FDA "Fast Track" designation for an autologous stem cell therapy delivered directly to the brain for Alzheimer's disease.

"Receiving 'Fast Track' designation from the FDA is an important milestone for RBI and a meaningful validation of the encouraging findings observed in our Phase I trial," said Christopher Duma, M.D., FACS, Founder and President of Regeneration Biomedical. "We believe this designation recognizes the urgent need for innovative therapies that address Alzheimer's disease through mechanisms beyond any single pathological pathway."

Dr. Duma continued, "Our direct-to-brain platform is designed to bypass the blood-brain barrier and deliver a patient's own stem cells throughout the central nervous system. We believe Alzheimer's disease is a whole-brain disorder requiring a comprehensive therapeutic approach—one capable of influencing neuroinflammation, tau biology, amyloid processing, and neuronal health simultaneously."

Based on the Phase I findings, the FDA recently cleared RBI to initiate a multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial. The study will evaluate repeated intracerebroventricular administration of RBI's autologous stem cell therapy every two months over a one-year period.

"While our Phase I study involved a single administration in six patients, the results gave us tremendous optimism," Dr. Duma added. "The FDA's decisions to both grant 'Fast Track' designation and clear our Phase II trial provide strong momentum as we advance a rigorous placebo-controlled study designed to determine whether repeated direct-to-brain stem cell therapy can meaningfully alter the course of Alzheimer's disease."

RBI previously presented Phase I findings at the 2026 Annual Meeting of the International Society for Cell & Gene Therapy (ISCT) in Dublin, Ireland, where the company reported sustained improvements in CSF proteomic markers and exploratory cognitive outcomes following treatment.

About Regeneration Biomedical, Inc.

Regeneration Biomedical, Inc. is a clinical-stage biotechnology company based in Newport Beach, California, developing autologous stem cell therapies for neurodegenerative diseases. RBI's proprietary platform employs Wnt-activated adipose-derived stem cells delivered directly to the brain through intracerebroventricular administration, bypassing the blood-brain barrier and

enabling broad distribution throughout the central nervous system. The company's lead program targets Alzheimer's disease, with additional research programs exploring applications in other neurodegenerative disorders.

Forward-Looking Statements

This press release contains forward-looking statements regarding RBI's investigational therapies, clinical development plans, regulatory interactions, and future clinical trials. Actual results may differ materially from those expressed or implied by these statements. RBI undertakes no obligation to update any forward-looking statements except as required by law.

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