# Exclusive: Safe, Direct-to-Brain Autologous Stem Cell Therapy Shows Promise in Alzheimer's

*A Phase 1, "first-in-mankind" trial of stem cells injected directly into the brain, is safe with early signs of efficacy; FDA submission made for Phase 2 trial.*

NEWPORT BEACH, CA, UNITED STATES, August 25, 2025 /EINPresswire.com/ -- Regeneration Biomedical, Inc. (RBI), a pioneering biotechnology company developing stem cell therapies for neurodegenerative diseases, today announced results of its FDA-cleared Phase 1 trial evaluating the world's first direct brain injections of autologous, Wnt-activated stem cells for Alzheimer's disease. The company has submitted its Phase 1 results to the FDA in support of initiating a Phase 2 multicenter, placebo-controlled trial.

The Phase 1 study, conducted at Hoag Memorial Hospital in Newport Beach, CA, involved six participants with mild to moderate Alzheimer's disease. Each received an infusion of their own ex vivo expanded, Wnt-activated, adipose-derived stem cells in escalated doses. This was achieved by administering the cells through an implanted Ommaya reservoir directly into the brain's ventricular system—bypassing the blood-brain barrier and allowing the cells to percolate throughout the brain.

The trial's primary endpoint of safety was achieved with a clean profile: no adverse events were observed that were directly attributable to the stem cell injection over 12–72 weeks. Secondary endpoints showed promising early efficacy signals at 12 weeks: p-Tau improved in 80% of evaluable participants, amyloid PET centiloid scores decreased in 60%, ADAS-cog cognitive scoring improved in 80%, and MMSE improved in 60%.

"These are results the field has never seen before; certainly with a single agent. After decades of failed Alzheimer's treatments, our approach not only proved safe but also showed measurable cognitive and biomarker improvements," said Christopher Duma, M.D., FACS, neurosurgeon, inventor, and Founder & President of Regeneration Biomedical, Inc. "What makes this therapy unique is that we deliver the patient's own stem cells directly into the brain, bypassing the blood-brain barrier, so they can reach every nook and cranny where Alzheimer's does its damage. This represents a disruptive paradigm shift in the treatment of Alzheimer's disease."

Why it's different

- Direct-to-brain vs. IV antibodies: Recently approved monoclonal antibodies (Biogen/Eisai's

Leqembi/lecanemab and Eli Lilly's Kisunla/donanemab) are administered IV and carry known risks of amyloid-related imaging abnormalities (ARIA) and infusion-related reactions; they require baseline and frequent MRI monitoring per FDA labels. RBI's autologous stem cells are delivered intraventricularly to bypass the blood-brain barrier and distribute broadly via cerebrospinal fluid. (FDA Access DataU.S. Food and Drug Administration.)

• Factual safety context for antibodies (per FDA labels): In Leqembi's pivotal study, ARIA-E occurred in 13% and ARIA-H in 14%, and infusion-related reactions in 26%, vs 2%, 8%, and 7% on placebo. Kisunla reported any ARIA in 36% (ARIA-E 24%, ARIA-H 31%) and infusion reactions 9% in Study 1; with a gradual dosing regimen (Study 2), ARIA-E ~16% and infusion reactions 16% were observed. MRI monitoring is specified before the 2nd, 3rd, 4th, and 7th infusions for Kisunla. (FDA Access Data U.S. Food and Drug Administration FDA Access Data.) There have been no such adverse events with the RBI cells.

• Leqembi and Kisunla do not improve cognition, they only slow the cognitive deterioration. RBI's autologous cells appear to improve cognition in this very early study.

• Independent media context: At CTAD 2024, BioSpace covered RBI's direct-to-brain approach and early signals (reduced p-Tau and amyloid, MMSE trending up in the initial cohort) alongside discussions of ARIA risk with antibody therapies. https://www.biospace.com/drug-development/leqembi-kisunla-and-beyond-the-next-wave-of-alzheimers-at-ctad-2024

Important note: Mechanisms differ (cell therapy vs. antibodies), and cross-trial comparisons have limitations. RBI's Phase 1 was designed primarily for safety with a small, open-label cohort; findings are preliminary and will be tested in a larger, controlled study.

Looking Ahead: Phase 2 Trial
RBI has submitted its Phase 1 findings to the FDA and is preparing to launch a multi-site, placebo-controlled Phase 2 trial in the United States, and is pioneering autologous stem cell therapies for Alzheimer's disease and other neurodegenerative conditions. Additional trials for Parkinson's disease, ALS, multiple sclerosis, and chronic traumatic encephalopathy (CTE) are also planned.

About Regeneration Biomedical, Inc.
Founded in 2018 by neurosurgeon Christopher Duma, M.D., FACS, Regeneration Biomedical, Inc. is building on preclinical and early clinical experience. RBI is advancing first-in-human disruptive approaches aimed not only at slowing disease progression but at restoring brain function.

Media Contact
Christopher Duma, MD, FACS
Regeneration Biomedical, Inc.
Email: chris@regenerationbiomedical.com
Phone: 949-689-9529

www.regenerationbiomedical.com

Christopher Duma
Regeneration Biomedical, Inc.
+1 949-689-9529
CHRIS@REGENERATIONBIOMEDICAL.COM
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Facebook
X

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