RBI, Inc. to Present their Phase 1 First-in-Human, Direct-to-Brain Autologous Stem Cell Therapy Results at CTAD 2025

Addressing the need for alternative approaches to the treatment of Alzheimer's disease, RBI takes a different route - direct injection into the brain.

SAN DIEGO, CA, UNITED STATES, December 1, 2025 /EINPresswire.com/ -- Regeneration Biomedical, Inc. (RBI) (www.regenbiomed.com), a pioneer in regenerative stem cell therapeutics for neurodegenerative diseases, announced today that it will present full Phase 1 clinical results of its first-in-human direct-to-brain autologous stem cell therapy for Alzheimer's disease at the Clinical Trials on Alzheimer's Disease (CTAD) annual meeting in San Diego. The presentation will occur today, Monday, December 1st, immediately following the CTAD embargo lifting at 3:00 PM PT.

> "With the completion of this Phase 1, RBI advances into Phase 2 and continues its mission to develop a regenerative therapeutic that may restore, not just preserve, neural function"
>
> *Bill Miller, CEO*

Clinical Phase 1 safety data will be presented from a study in which a patient's own stem cells—selected for high Wnt expression—were injected directly into the brain's ventricles. Wnt signaling is associated with activation of dormant neural stem cells, suggesting a regenerative pathway fundamentally distinct from current Alzheimer's drug strategies.

Following review of Phase 1 results, the U.S. Food and Drug Administration (FDA) has granted clearance for RBI to advance into Phase 2, a 115-patient, five-center clinical trial in the United States.

CTAD 2025: A Stage for Breakthrough Clinical Science

CTAD is the leading global venue for late-breaking results in Alzheimer's research, particularly as the field grapples with the shortcomings of multiple high-profile therapeutic approaches.

"We are honored to share our Phase 1 findings at CTAD," said Christopher Duma, MD, FACS, Founder of RBI and inventor of the direct-to-brain delivery method. "Our therapy uses autologous stem cells enriched for Wnt expression, with the goal of stimulating dormant ventricular stem cell populations. The feasibility, safety, and early cognitive signals observed in this first-in-human study underscore the urgent need for regenerative strategies."

Major Setbacks in Alzheimer's Drug Development Highlight Need for New Approaches

In just the past week, the field has seen additional setbacks:

- Johnson & Johnson's AUTONOMY trial of its anti-tau monoclonal antibody reported no clinical benefit, adding to a long list of failed tau-targeting programs.
- Novo Nordisk's GLP-1 Alzheimer's study, testing a metabolic/incretin-based strategy, also failed to demonstrate efficacy.

These results follow earlier limitations seen with FDA-cleared amyloid-targeting drugs — including Kisunla (donanemab, Eli Lilly) and Leqembi (lecanemab, Eisai/Biogen) — which reduce plaque but do not improve cognition and carry significant safety risks, including ARIA-related edema and hemorrhage.

Collectively, these failures highlight the need for novel mechanisms that go beyond amyloid, tau, or metabolic pathways.

RBI's Regenerative Platform: A New Therapeutic Category

RBI's direct-to-brain approach bypasses biological delivery barriers and introduces Wnt-selected autologous stem cells directly into the ventricular system. This strategy is designed to potentially:

- activate dormant endogenous neural stem cell pools,
- support structural repair of neuronal networks, and
- influence cognitive function via regenerative mechanisms.

While still unproven, early biological and cognitive signals from Phase 1 support advancing to larger clinical trials.

Phase 2: Scaling Toward a Regenerative Therapeutic

With FDA clearance in hand, RBI is initiating its 110-patient multisite Phase 2 clinical trial, and — importantly — because this represents full Phase 2 clearance of our delivery platform from the FDA, RBI can now translate its Phase 1 results directly into Phase 2 trials for additional neurodegenerative and neurological conditions, including ALS, multiple sclerosis (MS), Parkinson's disease, chronic traumatic encephalopathy (CTE), and stroke., which will further assess safety and explore cognitive outcomes across diverse patient populations.

"With this FDA clearance, RBI advances into Phase 2 and continues its mission to develop a regenerative therapeutic that may restore, not just preserve, neural function," said Bill Miller, CEO. "We are actively seeking strategic investment from family offices, institutional partners, and individuals committed to changing the trajectory of Alzheimer's disease."

About Regeneration Biomedical, Inc.

Regeneration Biomedical, Inc. (RBI) is a biotechnology company pioneering regenerative stem cell applications for Alzheimer's disease and other neurodegenerative conditions including ALS, MS, Parkinson's disease, and CTE. RBI was founded and led by neurosurgeon Christopher Duma MD, FACS, who also acts as President and Chairman of the Board, CEO Bill Miller and COO Robert Lynn.

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