

Regeneration Biomedical, Inc. to Present First-in-Human Direct-to-Brain Autologous Stem Cell Therapy Data at CTAD 2025

RBI's treatment injects a patient's own Wnt-expressing stem cells directly into the brain's ventricles—Results of their completed Phase 1 Trial are presented

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With this Phase 1 complete, RBI advances into Phase 2 and moves closer to a new therapeutic category for AD and other neurodegenerative diseases, like ALS, MS, Parkinson's disease, CTE, and stroke.”

Bill Miller, CEO

Biomedical, Inc. (RBI) announced that it will present Phase 1 clinical results of the world's first direct-to-brain autologous stem cell therapy for Alzheimer's disease today at the Clinical Trials on Alzheimer's Disease (CTAD) meeting in San Diego.

RBI's treatment involves injecting a patient's own Wnt-expressing [stem cells](#) directly into the brain's ventricles—an FDA-cleared, first-in-human neurosurgical delivery method designed to stimulate dormant endogenous neural stem cell populations.

Following review of the Phase 1 findings, the FDA has granted clearance for RBI to advance to Phase 2, a 110-patient, five-center U.S. clinical trial.

“CTAD is where major therapeutic directions are shaped, especially as multiple conventional drug approaches continue to fall short,” said Christopher Duma, MD, FACS, Founder of RBI. “Our regenerative strategy aims not just to slow decline but to potentially activate intrinsic repair pathways in the brain.”

Recent failures—including Johnson & Johnson's AUTONOMY anti-tau program and Novo Nordisk's GLP-1 Alzheimer's study, along with the limitations of amyloid-targeting drugs Kisunla and Leqembi—underscore the need for new mechanistic approaches.

“With this FDA clearance, RBI advances into Phase 2 and moves closer to establishing a new therapeutic category for Alzheimer's and other neurodegenerative diseases,” said Bill Miller, CEO. “We are actively engaging with strategic investors to support Phase 2 execution and expansion into ALS, MS, Parkinson's disease, CTE, and stroke.”

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