RBI Advances World's First Direct-to-Brain Autologous Stem Cell Therapy for Alzheimer's Into Phase 2 Clinical Trial

Regeneration Biomedical's Phase 2 trial of novel direct-to-brain autologous stem cell therapy for Alzheimer's disease has cleared a 30-day review with the FDA.

Simple injection of the stem cells via a reservoir conduit to the brain

NEWPORT BEACH, CA, UNITED STATES, September 23, 2025 / EINPresswire.com/ -- Key Takeaways:

• Regeneration Biomedical's Phase 2 trial of a novel direct-to-brain autologous stem cell therapy for Alzheimer's disease has cleared a 30-day review period with FDA.

• Phase 1 was the first to inject stem cells directly into the brain's ventricles; results showed safety, feasibility, and early signs of cognitive improvement.

• Phase 2 will enroll approximately 115 patients across five U.S. medical centers to further assess safety and efficacy.

• Further studies are expected to demonstrate that this direct-to-brain autologous stem cell therapy will outperform current FDA-approved drugs by improving cognition without high complication rates.

• RBI is actively seeking funding from family offices, institutions, grants and individuals to support

Phase 2 and expand to other neurodegenerative diseases including amyotrophic lateral sclerosis (ALS), multiple sclerosis, Parkinson's, and chronic traumatic encephalopathy.

Regeneration Biomedical, Inc. (RBI) (www.regenbiomed.com), a pioneer in regenerative stem cell applications for neurodegenerative diseases, today announced the company is ready to start the Phase 2 of its first-in-mankind clinical trial using direct-to-brain autologous stem cell therapy to treat Alzheimer's disease. This milestone follows the positive preliminary results of the company's groundbreaking Phase 1 trial.

The Phase 1 study was the first ever in humans to use a patient's own stem cells injected directly into the brain's ventricles as a possible treatment for Alzheimer's — a "direct-to-brain" delivery

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>
> *Christopher Duma, MD, FACS*

method that bypasses traditional barriers and allows for precise targeting of neurodegeneration. Preliminary results demonstrated feasibility and safety, and importantly, provided early evidence of potential cognitive improvement — a result not seen with any currently available Alzheimer’s drugs.

By contrast, recently FDA-cleared drugs reduce amyloid plaque but have not demonstrated meaningful improvement in cognition. Currently available drugs also carry significant risks of adverse events, including brain swelling and bleeding (amyloid-related imaging abnormalities, or ARIA), leading to high complication rates.

RBI’s approach is based on a novel regenerative concept. While still under investigation, the hypothesized mechanism of action is that RBI’s “supercharged” stem cells may stimulate normally dormant stem cells that naturally reside in the walls of the brain’s ventricles — effectively “waking them up” to repair and regenerate damaged neuronal networks.

RBI will be advancing into Phase 2, which will involve five leading medical centers across the United States and enroll 115 patients. This phase will further assess safety and begin to evaluate whether this therapy can alter Alzheimer’s progression in a statistically meaningful way.

“Our entry into Phase 2 underscores the promise and rigor of our direct-to-brain methodology,” said Christopher Duma, MD, FACS, Founder of RBI and inventor of the novel direct-to-brain injection of stem cells for Alzheimer’s and other neurodegenerative diseases including amyotrophic lateral sclerosis (ALS), multiple sclerosis, Parkinson’s disease, and chronic traumatic encephalopathy. “Unlike current drugs, which only slow decline and carry high complication risks, our therapy has shown early signs of actually improving cognition — something the field has long awaited.”

“Our readiness to move forward represents more than just a clinical milestone — it validates our mission to pioneer a new class of regenerative therapies for patients who, despite the recent approvals of donanemab and lecanemab, still lack treatments that improve cognition and are not burdened by serious side effects,” said Bill Miller, CEO of RBI. “We are now preparing to scale this effort with a world-class Phase 2 program, and we welcome strategic investment from family offices, institutions, and qualified individuals who share our vision of transforming the future of Alzheimer’s and other neurodegenerative diseases.”

Alzheimer’s disease affects more than 6 million Americans and remains one of the greatest unmet needs in medicine. If successful, this therapy may become the first regenerative, direct-to-brain intervention capable of addressing the underlying cellular deficits of neurodegeneration.

About Regeneration Biomedical, Inc. (RBI)

Regeneration Biomedical, Inc. is a biotechnology company pioneering regenerative stem cell

applications for neurodegenerative diseases. Founded by Christopher Duma, MD, FACS, with leadership from CEO Bill Miller and COO Robert Lynn, RBI is advancing first-in-class therapies using autologous stem cells delivered directly to the brain to address Alzheimer's, ALS, MS, Parkinson's disease, and CTE. By pushing the boundaries of regenerative medicine, RBI aims to restore function and improve quality of life for patients worldwide.

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