



# Regeneration Biomedical to Present Data on First Two Subjects in a Phase I Clinical Trial of Stem Cell Therapy delivered directly into the brains of Patients with Alzheimer's Disease

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*Wnt-activated, autologous, expanded, adipose-derived stem cells administered directly into lateral ventricles of the brain via Ommaya reservoir implanted under the scalp to bypass blood brain barrier*

*Data to be presented at the Alzheimer's Association International Conference (AAIC), 8 a.m. EDT, July 28, 2024*

NEWPORT BEACH, Calif., July 28, 2024 (GLOBE NEWSWIRE) -- Regeneration Biomedical, Inc. ("RBI"), a clinical-stage company developing autologous stem cell treatments for neurodegenerative diseases, today announced a presentation on early data on the first two subjects from a Phase 1 clinical trial of Wnt-activated, autologous, expanded, adipose-derived stem cells (RB-ADSCs) administered directly into lateral ventricles of the brain in patients with Alzheimer's Disease (AD). The data will be presented at the Alzheimer's Association International Conference (AAIC) in Philadelphia at 8 a.m. EDT, July 28, 2024.

"There has been significant investment to find an effective treatment for AD," said Christopher Duma, M.D., F.A.C.S., president, founder of RBI and presenter of the data. "However, recently approved anti-beta amyloid antibodies only slightly reduce the rate of cognitive decline at the risk of significant side effects. We are taking a very different approach using adipose-derived stem cells infused directly into the lateral ventricles to bypass the blood brain barrier (BBB). *In vivo* studies demonstrated that stem cells injected in this fashion do locate into the ventricles and

parenchyma. In addition, an IRB-approved pilot study of an earlier version of our stem cell product in patients with advanced neurodegenerative diseases generated promising results. We are presenting early results from this single ascending dose, first-in-human Phase 1 trial. Though the first two patients were treated at the lowest dose based on the protocol, we have seen intriguing results on AD biomarkers, which we will share during our presentation.”

Title:	Intracerebroventricular injection of autologous, Wnt-activated, adipose-derived stem cells for the treatment of Alzheimer’s Disease: Experience with the first two patients of a “First in Human” Phase 1 FDA trial
Session:	Developing Topics: Drug Development
Poster #:	94645
Time:	8 a.m. to 4:15 p.m. EDT
Date:	July 28, 2024
Room:	Exhibit Hall (Hall BC)

This FDA-cleared, Phase 1 open-label, single-arm study will enroll nine subjects over approximately one year randomized into a 3 + 3 dose escalation design to evaluate the safety of autologous RB-ADSC infused into the lateral ventricles of the brain in subjects with mild-to-moderate AD, and to determine a recommended dose for a potential Phase 2 clinical trial. Secondary endpoints include AD clinical assessments and biochemical and anatomical biomarkers. Each participant will be followed for up to 12 months after treatment. More information on the clinical trial can be found at [NCT05667649](https://clinicaltrials.gov/ct2/show/study/NCT05667649).

RB-ADSC are Wnt-activated adipose-derived stem cells obtained from a patient’s own adipose tissue. After collection, the stem cells are cultured and expanded *in vitro*, selected for Wnt expression, which is a signaling protein known to stimulate stem cells to communicate with other stem cells, and then reintroduced into the same patient via an Ommaya reservoir implanted under the scalp, which has direct access to one of the lateral ventricles located in the brain. Research in two animal models has demonstrated that stem cells infused into the ventricular system distribute themselves into brain parenchyma. In addition, no inflammation, obstruction of cerebral spinal fluid circulation or other safety signals were observed.

### **About Regeneration Biomedical**

Regeneration Biomedical, Inc. leverages world-class capabilities in stem cell therapy development and clinical application to develop autologous stem cell treatments for neurodegenerative diseases. Our proprietary therapy is derived from a patient’s own fat cells, which is a first-in-class

Adipose-Derived Stem Cell (ADSC) population. We also employ a proprietary isolation-expansion-enrichment manufacturing protocol to synthesize the therapy and inject it directly into the brain. For more information on Regeneration Biomedical, please visit [www.regenerationbiomedical.com](http://www.regenerationbiomedical.com).

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