South Florida Hospital News and Healthcare Report
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Longeveron Announces Initiation of Phase 2a Clinical Trial of Lomecel-B for the Treatment of Alzheimer's Disease

Trial designed to obtain safety and efficacy data of single and multiple dosing regimen

January 05, 2022 – Longeveron Inc. (NASDAQ: LGVN) ("Longeveron" or the "Company"), a clinical stage biotechnology company developing cellular therapies for

chronic aging-related and certain life-threatening conditions, announced today the initiation of its Phase 2a clinical trial evaluating Lomecel-B as a treatment for Alzheimer's disease (AD). The first patient has consented to participate in the trial and patient screening has begun.

This Phase 2a study is intended to build on encouraging preliminary Phase 1 data that were announced in 2021. Additionally, the Phase 2a trial is designed to measure brain anatomy using MRI, and include detailed assessments of the inflammatory and vascular systems thought to contribute to the worsening of AD. The study, which will be conducted at a minimum of 6 centers, is led by Mark L. Brody, MD, of Brain Matters Research, Delray Beach, Florida.

"This is an important next step in the progress of our Alzheimer's disease clinical program," said Geoff Green, CEO of Longeveron. "We are pleased to have initiated this Phase 2a trial, as this study is intended to build upon the Phase 1 results and marks an important milestone in our efforts to explore the therapeutic potential of Lomecel-B in AD," Green added.

Dementia resulting from AD is associated with vascular function decline and involves a pro-inflammatory state. In Longeveron's prior Phase 1 trial, Lomecel-B treatment met the primary safety endpoint, with no safety concerns – including no evidence of Alzheimer's-related imaging abnormality, known as ARIA. In addition, the levels of certain pro-vascular and anti-inflammatory biomarkers increased in the Lomecel-B treated subjects compared to placebo.

The Phase 2a trial is a double-blind, randomized, placebo-controlled design investigating safety and tolerability, as well as secondary endpoints that include cognitive function and biomarkers, following single or multiple infusions of Lomecel-B compared to placebo, in individuals with mild AD. The study consists of 4 treatment arms of 12 patients each,

for a total target enrollment of 48 patients.

About Longeveron Inc.

Longeveron is a clinical stage biotechnology company developing cellular therapies for specific aging-related and life-threatening conditions. The Company's lead investigational product is the LOMECEL-B™ cell-based therapy product ("Lomecel-B"), which is derived from culture-expanded medicinal signaling cells (MSCs) that are sourced from bone marrow of young, healthy adult donors. Longeveron believes that by using the same cells that promote tissue repair, organ maintenance, and immune system function, it can develop safe and effective therapies for some of the most difficult disorders associated with the aging process and other medical disorders. Longeveron is currently sponsoring Phase 1 and 2 clinical trials in the following indications: Aging Frailty, Alzheimer's disease, the Metabolic Syndrome, Acute Respiratory Distress Syndrome (ARDS), and hypoplastic left heart syndrome (HLHS). The Company's mission is to advance Lomecel-B and other cell-based product candidates into pivotal Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community. Additional information about the Company is available at www.longeveron.com.

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