Longeveron LLC Announces Completion of Enrollment in Phase 2b Clinical Trial of Longeveron Allogeneic Mesenchymal Stem Cells (LMSCs) in Aging Frailty.

NEWS PROVIDED BY
Longeveron LLC →
Feb 12, 2020, 12:05 ET

MIAMI, Feb. 12, 2020 /PRNewswire/ -- Longeveron LLC, a leading developer of adult stem cell technologies for aging-related and life-threatening conditions, announced today that it has completed enrollment in its Phase 2b Aging Frailty trial. This double-blinded, randomized, placebo-controlled study is designed to evaluate the safety and efficacy of LMSCs in patients with mild to moderate frailty.

This 150 subject multicenter study is sponsored in part by a Small Business Innovation Research (SBIR) Grant from the National Institute of Aging (NIA), as part of the Geroscience initiative focused on preventing and treating age-related conditions, functional decline, and disability.

"We are extremely pleased to achieve this significant enrollment milestone," said Geoff Green, President of Longeveron. "This study is designed to determine whether the transplant of healthy donor-derived mesenchymal stem cells can restore mild to moderately frail patients to a state of more healthful aging, thereby improving functionality and lowering their risk of disability, and dependence on others for care."

Aging Frailty is a life-threatening geriatric condition affecting millions of Americans over the age of 65. Frail elderly individuals are vulnerable to poor clinical outcomes compared to their age-matched peers despite sharing similar comorbidities and demographics. Clinically, frailty manifests as a combination of symptoms that includes loss of muscle and decreased strength, slowed walking, low activity and energy levels, poor endurance, nutritional deficiencies, weight loss and fatigue. Collectively, these lead to overall decline in functionality, and increased risk of disability, dependency, and death.

"The biology of frailty is complex, and includes diminished stem cell activity, reduced ability to repair and regenerate tissue, and chronic systemic inflammation," said Dr. Anthony Oliva, Senior Scientist at Longeveron and Principal Investigator of the NIA SBIR grant. "LMSCs have multiple mechanisms of action that can potentially address all of these issues, and thus make them extremely attractive as a therapeutic candidate for the unmet medical need of Aging Frailty."

"A recent study by Orkaby at al. of 3 million patients at the US Veterans Health Administration [VHA] showed that at least 1 in 3 older Veterans had Aging Frailty. The study also demonstrated a strong association of frailty with mortality in the older Veteran population" said Dr. Jorge G. Ruiz, Associate Director for Clinical Affairs at the Miami VA Healthcare System, Geriatric Research, Education and Clinical Center (GRECC) and University of Miami Miller School of Medicine, and lead clinical investigator on Longeveron's multi-site study. "Because of these concerns, the Miami VA Healthcare system screens patients for frailty and has established several Frailty Interventions and Treatments (FIT) clinics."

It is anticipated that the final trial results will become available in the first half of 2021. Subjects were enrolled from 8 clinical trial sites and randomized to receive a single peripheral intravenous infusion of LMSCs (25 million, 50 million, 100 million or 200 million cells), or placebo. The primary objective of the study is to assess the effect of LMSC treatment on exercise tolerance and endurance via the six-minute walk test (6MWT). Additional endpoints include gait speed, grip strength, short physical performance battery (SPPB), Performance Oriented Mobility Assessment (POMA) fear and risk of falling, depression, sexual function, cognition, and various patient reported outcomes (PROs) and activities of daily living (ADLs), and blood-based biomarkers.

Longeveron Allogeneic Mesenchymal Stem Cells (LMSCs) is a regenerative medicine product sourced from the bone marrow of young healthy adult donors. LMSCs are culture expanded under current good manufacturing practices (cGMP) to high standards, and maintained as individual "off-the-shelf" doses.

About Longeveron LLC

Longeveron (www.longeveron.com) is a regenerative medicine therapy company founded in 2014. Longeveron's mission is to provide biological solutions for aging-related diseases and life-threatening conditions, and is dedicated to developing safe and effective cell-based therapeutics for unmet medical needs such as Aging Frailty, the Metabolic Syndrome, Alzheimer's Disease and congenital heart defects in children (hypoplastic left heart syndrome).

For additional information please contact:

James Clavijo
Chief Financial Officer
Longeveron, LLC
jclavijo@longeveron.com
305-909-0840

SOURCE Longeveron LLC

Related Links

http://longeveron.com