

A vertical fluorescence microscopy image showing several cells. The cells are stained with a blue dye, likely DAPI, which highlights the nuclei. Within the nuclei, there are bright red spots, possibly representing specific proteins or markers. The background is a dark blue, and there are some lighter blue, fibrous structures visible. The overall image has a scientific and biological feel.

STEM CELLS *and* AGING

LONGEVERON

Biological Solutions for Aging

WHAT *is* AGING FRAILTY?

All human beings have reservoirs of stem cells in their bodies. Throughout life, these cells replenish the body, maintaining its health and vibrancy. As people age, their own stem cells become depleted. This occurs at different rates, and people who lose cells faster than others develop a medical condition called Aging Frailty. In addition to losing stem cells at a faster rate, people with Aging Frailty (and many other diseases) have an increased state of inflammation. This pro-inflammatory condition also contributes to Aging Frailty leading to a weakened immune system, more fatigue, difficulty going about daily activities, decreased physical functioning and mobility, increased visits to the doctor, and a general decrease in health and well-being without a definitive explanation or cause. One of the underlying triggers of frailty is the chronic low-grade inflammation within the body that naturally occurs with age.



HOW MIGHT LONGEVERON'S STEM CELL TREATMENTS HELP ME?

Scientists at Longeveron have shown that getting stem cell infusions derived from young, healthy donors may help alleviate this inflammation and may help individuals increase their mobility, strength and stamina by promoting tissue repair and regeneration and rebuilding their immune systems.

WHAT ARE LONGEVERON'S STEM CELLS?

Longeveron is working to develop biological solutions for aging and aging-related diseases through the use of its proprietary Longeveron Allogeneic Human Mesenchymal Stem Cells (LMSCs). LMSCs are stem cells produced from young, healthy human adult donor bone marrow, and are multipotent regenerative and restorative cells that may help to modulate the immune system. Longeveron manufactures its stem cells in its cGMP compliant facility located in Miami, Florida (cGMP refers to the Current Good Manufacturing Practice regulations enforced by the U.S. Food and Drug Administration (FDA)).

WHAT RESULTS HAS LONGEVERON PUBLISHED / IS THE TREATMENT SAFE?

Longeveron is currently the only organization conducting FDA-supervised clinical trials using stem cells to treat Aging Frailty and has five (5) open clinical trials in the United States (clinicaltrials.gov), including for Alzheimer's Disease and Aging Frailty. While we are currently conducting larger scale trials to evaluate the effects of the stem cell therapy, the results of our preliminary studies have been published in peer-reviewed medical journals. Patients in those early studies showed improved physical performance, strength and mobility, increased walking distance, improved cognition, increased Sexual Quality of Life (females), and decreased inflammatory markers in the blood.



Rationale & Design

Golpanian et al.
Oncotarget 2016.



Phase I Results

Golpanian et al.
J of Geron. 2017



Phase II Results

Tompkins et al.
J of Geron. 2017



Guest Editorial

Le Couture et al.
J of Geron. 2017

WHERE ARE LONGEVERON STEM CELL TREATMENTS AVAILABLE?

While there are no FDA approved stem cell treatments available in the United States, Longeveron is sponsoring FDA-supervised clinical trials for Aging Frailty in the United States which have open enrollment. These trials are being conducted at several leading hospitals including Stanford, Johns Hopkins, and the VA Hospital system, as well as in medical centers primarily in and around South Florida, for patients ages 70-85. In addition, Longeveron has received approval from the National Stem Cell Ethics Committee in the Bahamas to have a Treatment Registry in Nassau, Bahamas, for patients ages 60-95. The stem cells used in the U.S. clinical trials and the Bahamas Treatment Registry are the same (which we manufacture in our cGMP facility in Miami, Florida). The treatment is an intravenous infusion which takes less than an hour while you rest in a chair reading or watching television either at the U.S. Clinical Trial Sites or at the licensed medical facility in Nassau, Bahamas.



	U.S. CLINICAL TRIAL FOR AGING FRAILTY	BAHAMAS AGING FRAILTY TREATMENT REGISTRY
Age Range	70-85	60-95
Physical Condition (Frailty Score)	Mildly Frail patients to Moderately Frail patients are eligible	Well patients to Severely Frail patients are eligible
Stem Cell Dosage	Randomized, Placebo-Controlled trial, so a patient will either receive: <i>0 cells (Placebo) or 25 Million Cells or 50 Million Cells or 100 Million Cells</i>	Single-Arm Treatment Registry so all patients receive the same dose: <i>100 Million Cells</i>
Where are the Stem Cells made and where does the treatment take place?	The Stem Cells are produced in our cGMP facility in Miami and then shipped to the clinical trial site (primarily in South Florida area), where the infusion takes place.	The Stem Cells are produced in our cGMP facility in Miami and then hand-carried by our Director of Patient Services to the licensed medical facility in Nassau, Bahamas, where the infusion takes place.
How is the treatment delivered and how long does it take?	Intravenous infusion (~40 minute infusion) through a vein in your arm—no surgery, no overnight requirement	Intravenous infusion (~40 minute infusion) through a vein in your arm—no surgery, no overnight requirement
Frequency of Permitted Treatments	Single treatment	Treatment permitted up to every 6 months
Follow-up Visit Schedule	Required follow-up visits/testing at the clinical trial site at the following intervals: <i>1 month 3 months 6 months 9 months</i>	Requested follow-up visits with your home personal physician at the following intervals: <i>1 month 6 months</i>
Cost	No cost to patient	Paid for by patient

ABOUT LONGEVERON:

Longeveron is a leading global regenerative medicine company with a team of scientists, cell biologists, and other clinical and research staff, and a cGMP stem cell manufacturing facility located in Miami, Florida. Longeveron has licensed its stem cell technologies from the University of Miami Miller School of Medicine and its Interdisciplinary Stem Cell Institute, which has a 10 year track-record of advancing stem cell therapy in over 10 disease areas. To date, Longeveron has received \$7.5 Million in research grants for its clinical trials from the National Institute of Aging, TEDCO, and the Alzheimer's Association.

FOR MORE INFORMATION:

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