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STEM CELLS SHOW PROMISE IN THE TREATMENT OF FRAILTY

BARCELONA, SPAIN, April 28, 2017.

Stem cells from healthy young donors, delivered via intravenous infusion to frail older adults, were shown to reduce inflammation in a small pilot study reported today at the International Conference on Frailty and Sarcopenia Research (ICFSR). *"These findings suggest that stem cells may have the potential to reverse some of the most debilitating effects of aging that result from chronic inflammation and a decline in immune function",* according to Joshua M. Hare, M.D., Chief Science Officer of Longeveron LLC and Director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine.

Frailty, a multi-system syndrome that reflects decreased resilience to a range of stressors, has been increasingly recognized as a major cause of functional decline and adverse health outcomes in older adults. Chronic inflammation and other impairments in the immune system are thought to play a major role in the development of frailty. Adult stem cells derived from bone marrow – called mesenchymal stem cells (MSCs) -- have been shown to have potent anti-inflammatory properties. This trial tested the hypothesis that MSCs from the bone marrow of healthy young donors (called allogeneic cells – allo-hMSCs -- because they come from an unrelated donor) would reduce inflammation and improve function in frail older adults.

The trial enrolled 15 participants, aged 60-95, who met frailty criteria established by the Canadian Study on Health and Aging. Participants were randomized into three groups that received intravenous infusions of 20, 100, or 200 million allo-hMSCs. The infusions were well tolerated, with no treatment-related serious adverse events. Blood tests at baseline and at 6 and 12 months after the infusions showed a dose-related reduction in markers of inflammation as well as a decreased number of "exhausted" B cells. B cells are the immune cells responsible for producing

antibodies in response to infection, and the exhaustion of B cells along with age-related declines in other aspects of immune function results in "immunosenescence," characterized by impaired response to vaccines and increased susceptibility to infections. Since the group receiving 100 million allo-hMSCs showed the best response, a second infusion at that dose was given at 12 months, resulting in continued improvement of inflammatory and immune markers and suggesting a revitalization of the immune system.

"This is extremely important because what happens as we age is that we have a chronic low level of inflammation. With MSCs, not only are we reducing serum levels of inflammatory molecules but also reversing immunosenescence." said Ana Marie Landin, PhD, a scientist at the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine, and first author of this study.

The investigators will present additional data from this study – including data on changes in physical function and quality of life -- at a poster session on Saturday, April 29th, at 10:30 a.m. Building on the positive results in the pilot study, the team moved on to a larger, randomized placebo controlled trial. Results of that study will be published in the near future in the Journal of Gerontology. Co-authors of this study (www.clinicaltrials.gov: #NCT02065245) include Principal Investigator Joshua M. Hare, MD, Chief Science Officer of Longeveron LLC and Director of the Interdisciplinary Stem Cell Institute (ISCI) at the University of Miami Miller School of Medicine ; Audrey S. Medina and Anthony A. Oliva, PhD from Longeveron; Aisha Khan from ISCI; and Pascal Goldschmidt-Clermont, from the division of cardiology at the University of Miami Miller School of Medicine. Longeveron is a regenerative medicine company which focuses on disease of aging, including Alzheimer's disease, Aging Frailty, and the Metabolic Syndrome.

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