



CASE WESTERN RESERVE
UNIVERSITY
COLLEGE OF ARTS AND SCIENCES

SKELETAL RESEARCH CENTER

Case Western Reserve University
Department of Biology

LIVE WEBINAR

2022 CTTE SHORT COURSE

"Cell-Based Therapies and Tissue Engineering"

Keynote Lecture

"New insights into MSC activity in the CNS and in Aging Frailty: Results from studies using Lomecel-B"

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Longeveron, Inc.

University of Miami Miller School of Medicine



Lomecel-B is an allogeneic, culture-expanded bone-marrow derived MSC in phase 2 testing for Alzheimer's disease (AD) and aging frailty. Together these studies were designed to identify Lomecel-B bioactivity and pharmacology, to test safety in elderly populations and to explore provisional efficacy signals. In a phase 1 safety study of AD (n=33), Lomecel-B was well tolerated and did not cause any ARIA (Alzheimer's disease related imaging abnormalities) on MRI imaging. Results suggest evidence of potential CNS bioactivity with slowing of decline in cognitive function, assessed by the mini-mental score and the ADAS-Cog. Moreover, Lomecel-B appears to have stimulated an anti-inflammatory, pro-vascular milieu as evidenced by a panel of circulation cytokines. A second study was performed in subjects with mild to moderate aging frailty (n=148), designed to further assess bioactivity as well as biomarkers of efficacy. Participants were assigned to one of 4 doses of Lomecel-B, or placebo, in a randomized, double-blind fashion. The study supported safety and tolerability of single i.v. infusion. Importantly, the trial provided insight into bioactivity, in that a dose-response to Lomecel-B was evident at 6 months after infusion with regards to the primary endpoint of 6-minute walk distance. As with, the AD trial, the frailty study provided important mechanistic data from biomarker studies, particularly in the pro-vascular domain. Together these studies reveal important preliminary insights into Lomecel-B safety, tolerability and bioactivity in elderly populations afflicted with neurocognitive disorders and frailty. The findings provide important rationale and preliminary effect sizes for the design of future larger clinical trials.

Wednesday, May 25, 2022

5:00 – 5:45 p.m.

(This lecture is open to the University and its Affiliates)

For more information: txl116@case.edu or Visit our website: <http://cwru.edu/cttecourse>
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