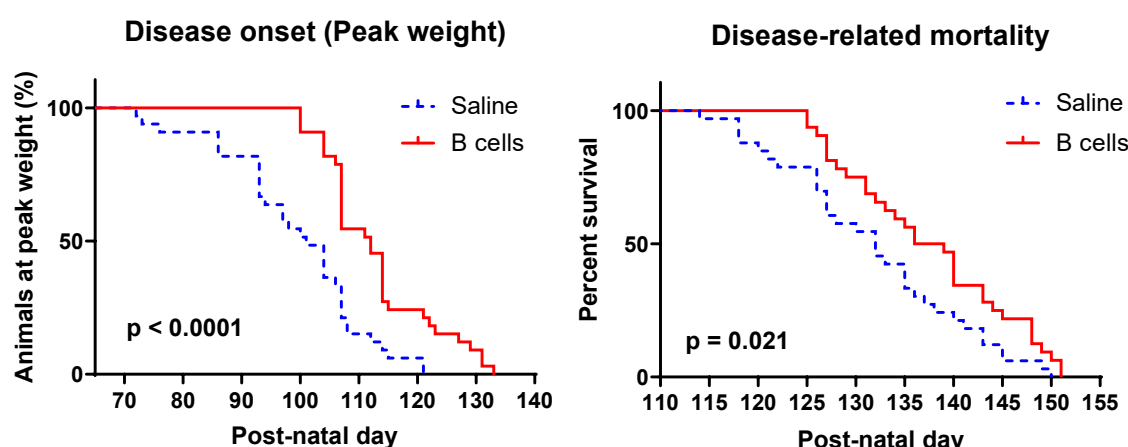
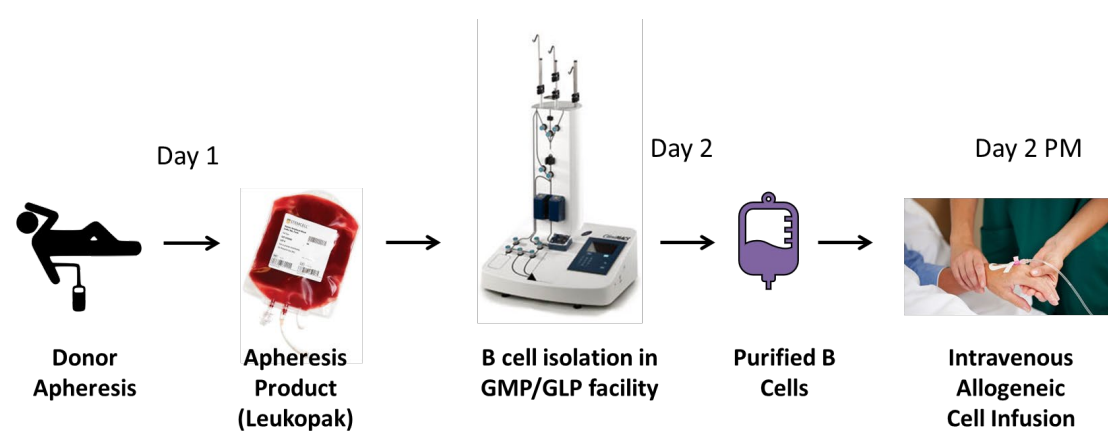
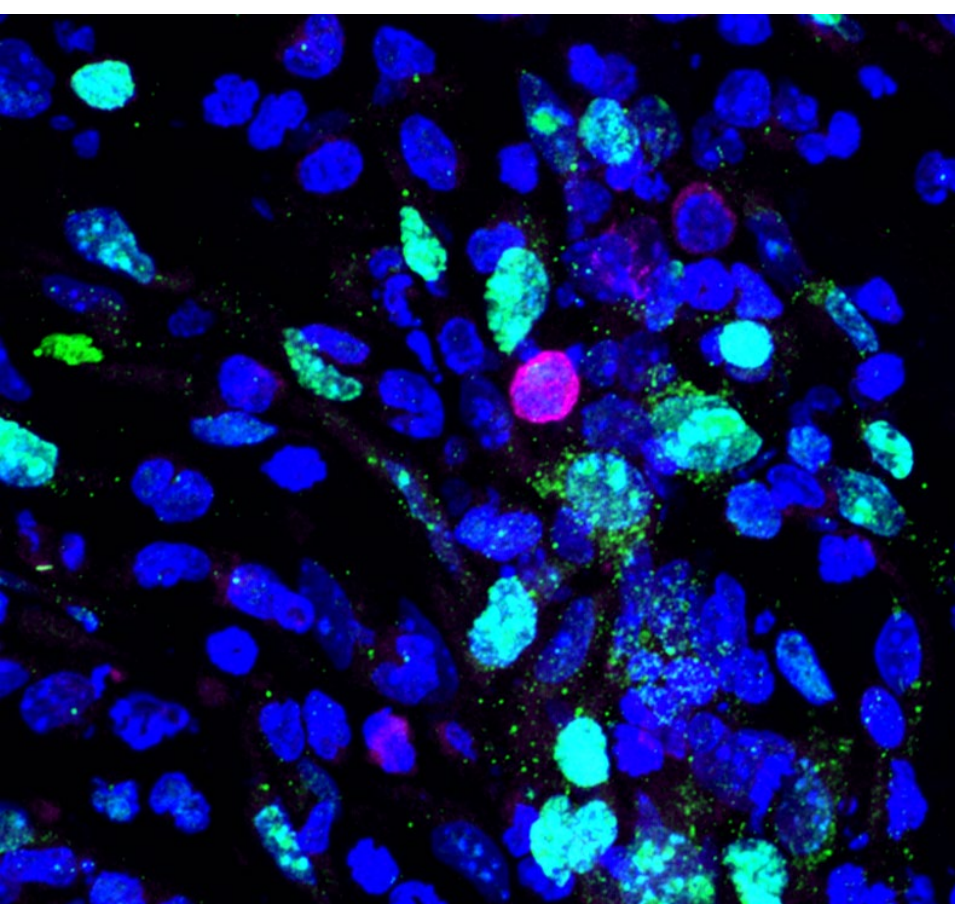


Allogeneic Naïve B Cells as a Novel Cell Therapy Candidate for Regenerative Medicine



Clinical Need

Stem and progenitor cells have been explored for regenerative medicine for over 40 years but there is a need for a scalable approach that can successfully advance through FDA review for commercial use.

Our Innovative Approach

Naïve B cells (NBCs) are fully developed, undifferentiated immune cells. They are abundant and accessible, making up 60-70% of the B cells in the peripheral blood (>5% of white cells in circulation). Further, they are genetically stable and short-lived, promoting safety *in vivo*.

We have shown that NBCs can modify phenotype and induce anti-inflammatory, immune-modulating, and tissue regenerative responses. They accelerate recovery from injury, promote functional improvement, and elicit neuroprotection. NBCs have shown therapeutic impact in mouse models of myocardial infarction, skin wounds, traumatic brain injury (TBI), acute respiratory distress syndrome (ARDS), intracerebral hemorrhage (ICH), and amyotrophic lateral sclerosis (ALS).

Results

In a well-established mouse model of ALS, weekly intravenous administration of NBC therapy over 10 wks was safe, delayed disease onset by up to 28 days and had a modest but significant effect on survival. NBCs also reduced hallmarks of ALS including cell death and glial scarring in the spinal cord.

In a human subject with ALS, two NBC infusions over two months proved safe with no clinically evident inflammatory response. After the first infusion, the subject's ALS functional rating score increased by 5 points. Further, a persistent reduction in inflammatory markers in the blood was observed. This study represents a first proof-of-concept showing the safety and feasibility of using NBCs as a therapeutic strategy for ALS.

Commercial Potential

We are optimizing an established GMP method of isolating NBCs from blood and have shown that NBCs maintain viability and function after extended low-temperature storage. We anticipate launching Phase 1 studies of NBC treatment in ALS and ICH in 2025.

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