

Docket #: S20-101

Novel NR1 ES-derived neural stem cell therapy for restoration of neurologic function following ischemic stroke

To date, there are no treatments to restore neurologic function for the 7 million US patients suffering from chronic ischemic stroke. NR1 therapy provides a novel treatment for this unmet need. Unlike the cells used in the SanBio and ReNeuron clinical stroke trials, which are genetically manipulated with the theoretic potential to form tumors, NR1 cells are not genetically altered. NR1 cells are the only allogeneic, non-genetically modified human neural stem cell intended for chronic stroke treatment, providing them with limitless manufacturing potential.

The Steinberg Lab at Stanford developed an NR1-based therapy to derive neural stems cells that can recover neurologic function following ischemic stroke. The treatment can be delivered intracerebrally into the area surrounding the chronic stroke. The secreted factors from the NR1 cells improve neurologic function by enhancing multiple native (molecular, cellular and circuit) mechanisms including modulation of the immune system, neovascularization and improving the excitatory/inhibitory balance of neural networks. Contrary to initial notions, they do not work through integration and cell replacement of neurons, astrocytes oligodendrocytes or other cells in the brain. The invention is currently undergoing Phase I/II clinical trials to demonstrate their clinical efficacy. Additionally, the therapy offers long viability after thawing compared to existing cellular therapies and already has a robust, scalable cGMP manufacturing process.

Stage of Development

Phase I/II Clinical Trial

Applications

- Treatment of ischemic stroke
- Treatment of traumatic brain injury and spinal cord injury
- Treatment of neurodegenerative diseases
- Neurological stem cell therapy

Advantages

- Only allogeneic, non-genetically modified human neural stem cell therapy method
- Longer viability after thawing than existing cellular therapies
- Robust, scalable cGMP manufacturing process

Publications

- ["A Safety and Tolerability Study of Neural Stem Cells \(NR1\) in Subjects With Chronic Ischemic Subcortical Stroke \(ISS\)"](#)

Patents

- Published Application: [WO2022081452](#)
- Published Application: [20230405054](#)

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