JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Study of Modified Stem Cells (SB623) in Patients With Chronic Motor Deficit From Ischemic Stroke

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Official Title: A Double-Blind, Controlled Phase 2b Study of the Safety and Efficacy of Modified Stem Cells (SB623) in Patients With Chronic Motor Deficit From Ischemic Stroke

This is a double-blind, sham-surgery controlled study of stereotactic, intracranial injection of SB623 cells in patients with fixed motor deficits from ischemic stroke.

Two cohorts, Group 1 (2.5 and 5 million SB623 cells combined) and Group 2 (sham placebo), will be included in this study. Subjects who are randomized into this study will receive either 2.5 million SB623 cells, 5 million SB623 cells or sham surgery at a 1:1:1 randomization ratio. Randomization will be performed via an interactive web/voice response system (IXRS), stratified by Screening Modified Rankin Scale (mRS) score (recorded in the IXRS at the clinical site).

SB623 cells are bone-marrow-derived stromal cells that have been transiently transfected with the intercellular domain of the human Notch-1 gene.

Key Inclusion Criteria:

- Age 18-75 years inclusive
- Documented history of completed ischemic stroke in subcortical region of MCA or lenticulostriate artery with or without cortical involvement, with correlated findings by MRI
- Between 6 and 90 months (7.5 years) post-stroke, and having a chronic motor neurological deficit due to the incident stroke
- Modified Rankin Score of 2-4 (2: Slight disability; able to look after own affairs without assistance. 3: Moderate disability, requires some help, but able to walk unassisted. 4: Moderately severe disability; unable to attend to own bodily needs without assistance, and unable to walk unassisted)