A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

Grant Award Details

A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-10344

Project Objective: A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke.

Investigator:

Name:	Bijan Nejadnik
Institution:	SanBio, Inc.
Type:	PI

Disease Focus: Neurological Disorders, Stroke

Human Stem Cell Use: Adult Stem Cell

Award Value: $18,970,000

Status: Active

Grant Application Details

Application Title: A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

Public Abstract:

Therapeutic Candidate or Device

Modified adult donor bone marrow-derived mesenchymal stem cells (Modified MSC)

Indication

Chronic motor deficit secondary to ischemic stroke

Therapeutic Mechanism

Local intracerebral delivery of Modified MSC adjacent to motor pathways stimulate via a paracrine mechanism neuropoiesis & angiogenesis by the release of FGF-2, other trophic factors & ECM proteins. The net effect is alteration of synaptic transmission appearing to improve motor function in a hitherto inhibitory milieu. Collectively, these properties are thought to promote neuroplasticity seen as the basis for improvement in motor function observed in stroke patients treated with Modified MSC.

Unmet Medical Need

There are no proven medical treatments available for chronic disability secondary to stroke. Results from our Phase 1/2a study suggest that Modified MSC has a favorable safety profile and the potential to improve motor function in these patients.

Project Objective

Complete Ph 2b trial; EOP2 meeting; Enable Phase 3

Major Proposed Activities

- Completion of Phase 2b ACTIsSIMA clinical trial.
- Manufacture Modified MSC clinical supplies.
- Further investigate and validate the mechanisms of action to identify additional measures of potency and validation of associated bioassays.

Statement of Benefit to California:

In 2012, 96,500 Californians suffered strokes with approximately 67,500 patients experiencing residual disabilities. Results from our Phase 1/2a study suggest that Modified MSC has a favorable safety profile and the potential to improve motor function in these Californians. This research will involve many clinical & research sites throughout California which will have a positive effect on the state's economy and scientific profile.

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