Study Factsheet

for Health Care Providers

Protocol Title	MultiStem® Administration for Stroke Treatment and Enhanced Recovery Study (MASTERS-2)
Protocol Number	B01-04
ClinicalTrials.gov Identifier	TBD (www.clinicaltrials.gov)
Phase of Development	Phase III, pivotal study
Study Treatment	MultiStem is an allogeneic, regenerative medicine advanced therapy (RMAT) being investigated for treatment of acute ischemic stroke within 36 hours after symptom onset. Subjects will receive a single IV infusion of 1.2 billion cells of MultiStem (or placebo).
Study Objective	• To evaluate the safety and efficacy of MultiStem on functional outcome (modified Rankin Scale) in subjects with ischemic stroke • To evaluate the efficacy of MultiStem on neurological, disability, mortality, secondary infection, and hospitalization outcomes in subjects with ischemic stroke • To evaluate the impact of MultiStem on quality of life in subjects with ischemic stroke
Study Overview	This is a pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter international study. The total study duration for each subject will be 12 months. Approximately 300 subjects who have experienced an acute cortical ischemic stroke and fulfill all the eligibility criteria will be enrolled into the study globally. Subjects will be randomized in a 1:1 ratio to receive either MultiStem or placebo.
Key Eligibility Criteria	• Male or female subjects 18 years of age or older • Clinical diagnosis of ischemic stroke involving cerebral cortex • Onset of stroke symptoms must have occurred 18 to 36 hours prior to the planned start of administration of the investigational product (Patient must enter screening within 28 hours of the onset of symptoms) • Moderate to moderately severe stroke with a stable NIHSS score of 8 to 20 (inclusive) • Confirmation of hemispheric cortical infarct by brain MRI or CT demonstrating an acute ischemic infarct volume between 5 and 100 ml • A modified Rankins Score of 0 or 1 (little or no disability) prior to the onset of symptoms of the current stroke, by either self reported history or by family/caregiver report

For more information about the MASTERS-2 study, please contact:

MASTERS-2

opening the window for stroke treatment

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