ALS ASSOCIATION Greater Sacramento Chapter

NurOwn: Brainstorm Cell Therapeutics are continuing to recruit for NurOwn Phase 3 trial. They are approximately ½ way recruited with 100 people enrolled. They plan to recruit through mid-2019. Below are the inclusion/exclusion criteria:

What are the inclusion criteria?

1. Males and females ages 18 to 60 years old, inclusive, at the Screening Visit.
2. ALS diagnosed as possible, laboratory-supported probable, probable, or definite as defined by revised El Escorial criteria.
3. Having onset of ALS disease symptoms, including limb weakness within 24 months at the Screening Visit.
4. ALSFRS-R ≥ 25 at the screening Visit.
5. Upright slow vital capacity (SVC) measure ≥ 65% of predicted for gender, height, and age at the screening Visit.
6. Decline in ALSFRS-R total score of 3 or more points in the three months before randomization.
7. Taking a stable dose of riluzole, or no riluzole at all (riluzole-naïve participants are permitted in the study), for at least 30 days prior to the Screening Visit and be willing to maintain the riluzole dose for the duration of the study.

What are the exclusion criteria?

1. Prior stem cell therapy of any kind.
2. Active participation in any other ALS interventional study
3. Inability to lie flat for the duration of intrathecal cell transplantation and/or bone marrow biopsy, or inability to tolerate study procedures for any other reason.
4. History of autoimmune disease that may confound study results myelodysplastic or myeloproliferative disorder, leukemia or lymphoma, whole body irradiation, hip fracture, or severe scoliosis.
5. Any unstable clinically significant medical condition other than ALS (e.g., within six months of baseline, had myocardial infarction, angina pectoris, and/or congestive heart failure), treatment with anticoagulants that, in the opinion of the investigator, would compromise the safety of participants.
6. Any history of malignancy within the previous 5 years, with the exception of non-melanoma localized skin cancers (with no evidence of metastasis, significant invasion, or re-occurrence within three years of baseline).
7. Current use of immunosuppressant medication or use of such medication within 4 weeks of Screening visit (Visit 1).
8. Any history of acquired or inherited immune deficiency syndrome.
9. Use of RADICAVA (edaravone injection) within 30 days of screening or intent to use edaravone at any time during the course of the study including the follow up period
10. Exposure to any other experimental agent (off-label use or investigational) or participation in a clinical trial within 30 days prior to Screening Visit (Visit 1).
11. Use of non-invasive ventilation (NIV), diaphragm pacing system or invasive ventilation (tracheostomy) at the screening or randomization visit.
12. Usage of feeding tube at the screening or randomization visit.
13. Pregnant women or women currently breastfeeding.