Pilot Phase 2 Trial of the Safety & Efficacy of GM-CSF (Leukine) in the Treatment of Alzheimer's Disease PI Huntington Potter, PhD COMIRB# 12-1273 Version November 17, 2016

Volunteers with Alzheimer's Disease Needed for Memory Study

What is the purpose?

• To examine the safety and efficacy of the study drug, Sargramostim (Leukine®), on memory in adults with Mild-to-Moderate Alzheimer's Disease

Who can potentially qualify to participate?

- Age range: 55 to 85 years;
- Individuals should have a mild-to-moderate Alzheimer's Disease Diagnosis (MMSE 10-26 inclusive);
- Individuals on anti-dementia treatment should be on stable treatment for at least 2 months (i.e. cholinesterase inhibitor and/or Memantine or Axona);
- Individuals should be stable on all other medications for at least 30 days prior to screening;
- Individuals should be fluent in English;
- Individuals should be physically able to participate by medical history, clinical exam and tests;
- Individuals should have a study partner who can accompany them to visits;
- Individuals who are on anti-dementia medications may still be able to participate

Who would not qualify to participate?

Individuals with a history of arrhythmias; a resting pulse less than 50; active cancer other than
non-melanoma skin cancers; using another investigatory drug within 2 months of screening;
significant stroke or head trauma by history or MRI; any contraindication for having a MRI; any
contraindication for having a PET scan; have a current major psychiatric disorder; sensitivity to
yeast or yeast products; impaired kidney function; preexisting fluid retention, pulmonary
infiltrates, or congestive heart failure; history of moderate-to-severe lung disease; history of
moderate-to-severe liver disease; pregnant women, or any women who feel they are likely to
become pregnant during the study; and prisoners are not eligible

What will you receive?

- Study drug injections, 5 days a week for 3 weeks (either Sargramostim or placebo)
- Cognitive testing
- MRI scans of the brain
- PET scans of the brain
- Blood work

Although the majority of the time needed to participate in this study is in the first month during the treatment period, individuals will be asked to participate in 2 follow up visits for a total study time of about 5 months.

For more information about this research study send an email to Nicola.haakonsen@ucdenver.edu or call 303-724-4644.