



Press Release

FDA Gives TCA Cellular Therapy Green Light to Proceed with First ALS Adult Stem Cell Trial...

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BusinessWire - TCA Cellular Therapy, LLC (TCA-CT) announced today that the U.S. Food and Drug Administration (FDA) has approved its adult stem cell protocol to conduct Phase I clinical trials to treat Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's disease)

This is the second FDA-approved protocol for the treatment of ALS using stem cells in the country; and the first using adult stem cells from the same patient. The aim of the Phase I study will assess safety

ALS afflicts approximately 30,000 Americans. More people die of ALS than Huntington's disease; and the fatalities nearly equal Multiple Sclerosis. The life expectancy of a patient diagnosed with ALS is two to five years.

"I hope that our trial, along with the combined efforts of scientists and patients, will pave the way to breaking the chains of this devastating disease," stated Gabriel Lasala, M.D., president and CEO of TCA Cellular Therapy.

About the Trial

Under the scientific guidance of cellular biologist, Jose J. Minguell, Ph.D., the adult stem cells will be taken from the patient's bone marrow in a simple outpatient procedure. The cells will then be processed in TCA-CT's GMP laboratory and administered to the patient by spinal tap in one of TCA-CT's facilities.

Recruitment for trial patients will commence in the next few weeks. The company anticipates moving into Phase II within a year.

About TCA Cellular Therapy

TCA Cellular Therapy, a privately-held company located in Covington, Louisiana, has assembled a team of neurologists, neurosurgeons, cell biologists, and pathologists to study some of the most debilitating neurological diseases including ALS and Spinal Cord Injuries.

SOURCE: TCA Cellular Therapy

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