Neuralstem, Inc., receives FDA approval for Phase 1 stem cell clinical trial

Prize4Life heralds FDA decision, congratulates researchers

Rockville, MD, and Cambridge, MA, September 21, 2009—Priz4Life congratulates Neuralstem, Inc., which announced that the FDA approved its application to conduct a Phase I safety trial of its stem-cell based approach to treat ALS. The FDA's approval makes Neuralstem the first company to commence a stem cell trial for ALS. The trial will examine the safety of Neuralstem's cells and the surgical procedures required for delivering multiple injections of these stem cells directly into the human spinal cord. The FDA's approval represents a significant step toward realizing the promise of stem cells for helping damaged neural cells in humans.

This trial will be led by Dr. Eva L. Feldman, M.D., Ph.D., Director of the University of Michigan Health System ALS Clinic and the Program for Neurology Research & Discovery, and Dr. Jonathan Glass, Director of the Emory Neuromuscular Laboratory and Director of the Emory ALS Center. Both researchers are renowned for their study and treatment of ALS patients.

About the Trial

The 18 ALS patients participating in the trial will be treated through a series of spinal injections of NeuralStem's patented human neural stem cells. This first trial will primarily evaluate safety of the cells and the surgical procedure. The FDA has approved the first stage of the trial, which will consist of 12 patients who will receive five-to-ten stem cell injections in the lumbar area of the spinal cord. The patients will be examined at regular intervals post-surgery, with final review of the data to come 24 months later.

Neuralstem expects to conduct the trial at Emory University with Dr. Jonathan Glass, M.D., as site Principal Investigator (PI) and with Dr. Nicholas Boulis, M. D. performing the neurosurgery. The overall PI for the ALS trial program will be Dr. Eva Feldman, M.D., Ph.D.

Neuralstem focuses on treatments for major central nervous system diseases, including ALS. Pre-clinical work has shown Neuralstem's cells to extend the life of rats with ALS (as reported in the journal *Transplantation*, October 16, 2006, in collaboration with Johns Hopkins University researchers), and also reversed paralysis in rats with Ischemic Spastic Paraplegia, (as reported in the journal *Neuroscience*, June 29, 2007, in collaboration with researchers at University of California, San Diego).

Prize4Life congratulates Neuralstem for its impressive work, and is excited to see the FDA take this important step towards actualizing stem cells as a potentially promising therapy. Prize4Life also congratulates BrainStorm Cell Therapeutics, of Petach Tikva, Israel, for its recently-secured funding to complete pre-clinical stem cell trials for ALS. A competitor for Prize4Life's Avi Kremer ALS Treatment Prize, BrainStorm expects to

begin Phase I clinical trials in early 2010. BrainStorm's new funding includes both a prestigious grant from the Israeli government's Office of the Chief Scientist, as well as private investment.

This FDA approval indicates a major change in the ALS landscape, making it easier for subsequent researchers to gain FDA approval and to move forward with testing other stem cell therapies. Prize4Life is thrilled on behalf of PALS, for whom Neuralstem's discovery may signal an advance towards lifesaving treatments.

About ALS

ALS is a rapidly progressing neurodegenerative disease that typically takes the life of patients within 2-5 years of diagnosis. It is caused by the degeneration of motor neurons, the nerve cells in the central nervous system that control voluntary muscle movement. It most commonly strikes people between the ages of 40 and 70, and affects men slightly more than women. ALS is the most common motor neuron disease worldwide, and as many as 30,000 Americans struggle with the disease at any given time. There is no known cure for ALS and only one FDA-approved treatment for the disease.

About Prize4Life

Prize4Life was founded by a group of Harvard Business School students when one of them, Avi Kremer, was diagnosed with ALS at the age of 29. Prize4Life works to accelerate the discovery of a treatment and a cure for ALS by using powerful incentives to attract new people and ideas, and to leverage existing efforts and expertise in the ALS field. Among other program initiatives, the organization currently administers the ALS Biomarker Prize Challenge, the Avi Kremer ALS Treatment Prize, and the ALS Forum.

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