BrainStorm Announces Clinical Data for Safety and Supporting Efficacy of NurOwn Based on Initial Phase I and II Results

New York, USA & Petach Tikvah, Israel - B3C newswire [1] - BrainStorm Cell Therapeutics Inc. [2], an innovative developer of adult stem cell technologies and Central Nervous System (CNS) therapeutics, today announced that the data from the initial patients in its ALS Phase I/II human clinical trial treated with its NurOwn™ technology did not present any significant side effects and that the NurOwn™ treatment has so far proven to be safe. Prof. Dimitrios Karussis, who is leading the clinical trial at Hadassah Medical Center, stated, "There have been no significant side effects in the initial patients we have treated with BrainStorms NurOwn™ technology. In addition, even though we are conducting a safety trial, the early clinical follow up of the patients treated with the stem cells shows indications of beneficial clinical effects, such as an improvement in breathing and swallowing ability as well as in muscular power. I am very excited about the safety results, as well as these indications of efficacy, we are seeing. This may represent the biggest hope in this field of degenerative diseases, like ALS."
After reviewing the safety data from the first four patients, the Hadassah Medical Center ethical committee granted approval for the trial to advance to transplanting the next patients.

"We are happy to report that the first patients treated with our NurOwn™ technology did not present any significant side effects. This supports and strengthens our belief and trust in our technology. Based on the interim safety report, the hospital ethical and safety committee granted the company approval to proceed with treating the next patients. We are pleased with the progress we are making and look forward to continuing to demonstrate the safety of NurOwn™ in the future," said Chaim Lebovits, BrainStorms President.

The ALS Phase I/II human clinical trial is being performed at Hadassah Medical Center in Israel in collaboration with BrainStorm and is utilizing BrainStorms NurOwn™ technology for growing and modifying autologous adult human stem cells to treat ALS, often referred to as Lou Gehrig's Disease. The study is headed by Prof. Karussis, M.D., Ph.D., who is the head of Hadassah's Multiple Sclerosis Center and a member of the International Steering Committees for Bone Marrow and Mesenchymal Stem Cells Transplantation in Multiple Sclerosis (MS), and a scientific team from BrainStorm headed by Prof. Eldad Melamed. The initial phase of the study is designed to establish the safety of NurOwn™ and will later be expanded to assess efficacy.

About Amyotrophic Lateral Sclerosis
Amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's Disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. According to the ALS Association, approximately 5,600 people in the

U.S. are diagnosed with ALS each year and it is estimated that as many as 30,000 Americans may have the disease at any given time.

About NurOwn™
BrainStorms core technology, NurOwn™, is based on the scientific achievements of Professor Eldad Melamed, former Head of Neurology, Rabin Medical Center, and Tel-Aviv University, and a member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research, and Professor Daniel Offen, Head of the Neuroscience Laboratory, Felsenstein Medical Research Center (FMRC) at the Tel-Aviv University.

The NurOwn™ technology processes autologous adult human mesenchymal stem cells that are present in bone marrow and are capable of self-renewal as well as differentiation into many other cell types. Adult human bone marrow cells are induced to differentiate into astrocyte-like cells capable of releasing neurotrophic factors, including glial-derived neurotrophic factor (GDNF) by means of a specific differentiation-inducing culture medium. The ability to induce differentiation into astrocyte-like cells along with intramuscular or intrathecal (or other) delivery makes NurOwn™ technology highly attractive for treating ALS and Parkinsons disease as well as MS and spinal cord injury.

About BrainStorm Cell Therapeutics, Inc. [2] [2]
BrainStorm Cell Therapeutics Inc. is a biotech company developing adult stem cell therapeutic products, derived from autologous (self) bone marrow cells, for the treatment of neurodegenerative diseases. The company, through its wholly owned subsidiary Brainstorm Cell Therapeutics Ltd., holds rights to develop and commercialize the technology through an exclusive, worldwide licensing agreement with Ramot at Tel Aviv University Ltd., the technology transfer company of Tel-Aviv University. The technology is currently in a Phase I/II clinical trials for ALS in Israel.

Posted by Sean Fenske, Editor-in-Chief, MDT

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