NeuroEM Therapeutics Receives Clinical Trial Approval to Test its Novel Head Device in Alzheimer's Patients

First U.S. study to test electromagnetic treatment against Alzheimer's

Phoenix, AZ (January 4th, 2016) NeuroEM Therapeutics, a Phoenix-based medical device company, announced today that it has received approval to conduct a Phase I clinical trial in Alzheimer's patients with its proprietary electromagnetic treatment. The Western Investigational Review Board (WIRB) granted that approval, along with designating NeuroEM's electromagnetic treatment device as a "non-significant risk" device. The FDA had previously provided constructive feedback to the design of the clinical trial.

"NeuroEM is pleased that it now has the green light to proceed forward with a Phase I clinical trial" said Dr. Gary Arendash, the company's Founder and CEO. "The trial will evaluate the safety and preliminary efficacy of this revolutionary approach to the treatment of Alzheimer's Disease". The study will be performed jointly by the Banner Sun Health Research Institute and Banner Alzheimer's Disease in Phoenix.

In NeuroEM's Phase I clinical trial, patients with mild to moderate Alzheimer's Disease will be treated daily in their own homes with the company's unique Transcranial Electromagnetic Treatment (TEMT) head device. The device allows for complete mobility during the two 1-hour treatment sessions per day, with the patient's caregiver overseeing device operation.

NeuroEM plans to pursue eventual FDA clearance of its TEMT head device through the *de novo* 510(k) regulatory pathway. Current FDA-approved drugs against Alzheimer's only treat the disease's symptoms without impacting the disease process itself. "No new Alzheimer's drugs have been approved by the FDA in the last 13 years and clinical trials involving new drugs against the disease have been universally disappointing" said Dr. Arendash. "It is time to investigate non-drug therapeutics against Alzheimer's and, to that point, we believe our electromagnetic technology may offer an excellent chance for stabilizing or possibly even reversing Alzheimer's memory impairment".

Dr. Arendash and colleagues have published multiple studies since 2010 demonstrating that electromagnetic treatment to Alzheimer's mice reverses their Alzheimer's-like memory impairment and neuropathology. In such pre-clinical studies, the researchers found strong evidence for "disease-modifying" effects not provided by any other therapeutic being tested against Alzheimer's. For example, TEMT disaggregates small aggregates (oligomers) of beta-amyloid inside brain cells – these small oligomers of beta-amyloid are now thought by many Alzheimer's researchers to be the real culprit for initiation and progression of the disease.

"In the new field of neuromodulation against neurodegenerative diseases, TEMT technology may be a promising approach against Alzheimer's Disease" commented Dr. Arendash.

“NeuroEM’s clinical trials will be critical in determining the true potential of TEMT against this dreaded disease”.

About NeuroEM Therapeutics, Inc.

NeuroEM Therapeutics is a medical device company focused on development of Transcranial Electromagnetic Treatment (TEMT) to treat neurodegenerative disorders such as Alzheimer’s Disease, Traumatic Brain Injury, and Down’s Syndrome. The company is headquartered in Phoenix, AZ, which is a hub of both pre-clinical and clinical investigation into neurodegenerative disorders and diseases. As such, NeuroEM Therapeutics is collaborating with leading institutions in the Phoenix area such as Banner Sun Health Research Institute, Banner Alzheimer’s Institute, and Arizona State University. For more information about NeuroEM Therapeutics, go to www.neuroem.com.

Forward-Looking Statements

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the projections, financial condition, results of operations and businesses of NeuroEM Therapeutics, are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements.