



Alzheimer's Memory Loss Reversed by Easy-to-Wear Head Device from NeuroEM Therapeutics

- *Results published in the Journal of Alzheimer's Disease suggest that two months of in-home transcranial electromagnetic treatment (TEMT) was safe and improved memory performance of patients with mild to moderate Alzheimer's disease (AD)¹*
- *After two months of treatment, memory decline in most patients appeared to have been reversed to cognitive levels equivalent to 12 months earlier¹*
- *Findings point to a potential breakthrough in AD treatment, with a larger pivotal study being planned to confirm these findings*

Phoenix, AZ (August 6th, 2019) – NeuroEM Therapeutics, a clinical stage medical device company focused on neurodegenerative diseases, today announced findings from an early stage study, which assessed safety and initial efficacy of transcranial electromagnetic treatment (TEMT) with the company's investigational MemorEM™ head device for Alzheimer's disease (AD). Results from the two-month trial demonstrate that TEMT was safe in all eight participating patients with mild to moderate AD and enhanced cognitive performance in seven of them, as measured by standard cognition scales¹. The study was published in the *Journal of Alzheimer's Disease*.

"This pioneering study suggests that TEMT may be an entirely new therapeutic intervention against Alzheimer's disease," said Dr. Gary Arendash, CEO of NeuroEM Therapeutics. "Our bioengineering technology may be succeeding where drug therapy against this devastating disease has thus far failed. TEMT appears to be affecting the Alzheimer's disease process through several actions directly inside neurons (brain cells), which is where we believe the disease process needs to be stopped and hopefully reversed."

The inability of pharmaceuticals thus far to effectively slow or reverse cognitive impairment of AD has led to the development of non-pharmaceutic neuromodulatory approaches, including TEMT, the newest such approach. TEMT is different from other neuromodulatory technologies, such as transcranial magnetic stimulation or transcranial direct current stimulation, since it uses both magnetic and electric waves. The study is the first to administer electromagnetic waves to the entire human brain over an extended period of two months.

"Despite significant efforts for nearly 20 years, stopping or reversing severe memory impairment in people with Alzheimer's disease has eluded researchers thus far," said co-author Amanda Smith, M.D., Director of Clinical Research, University of South Florida Health, Byrd Alzheimer's Institute, the clinical center for the study. "These results provide preliminary evidence that the neuromodulatory approach we assessed in this very small study may have the capacity to enhance cognitive performance in patients with mild to moderate disease."

Key Findings¹

After two months of treatment administered at home by a caregiver, none of the eight patients in the study exhibited any recurrent changes in eating or drinking, daily movement activities or anxiety level/mood, as recorded by caregivers in daily diaries. No patient complained of headaches, brain sensations or any other TEMT side effects during or following treatment. Assessments conducted at the clinic throughout the study found no treatment-related adverse events (AEs) and no suicide tendencies. Additionally, post-treatment brain scans revealed no visible induction of tumors or brain bleedings called microhemorrhages.

An initial efficacy analysis showed that the seven patients who responded to TEMT had a clinically important combined increase in cognitive performance at the end of the two-month treatment period, as measured with the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-cog) and effect size (ES).^{*} ES=1.21; $p<0.02$. This corresponded to an average 4.1 point improvement on the ADAS-cog, a widely used clinical assessment tool in AD. Improved cognition was generally maintained at two weeks after treatment completion, consistent with an effect on the disease process itself: ES=1.01; $p<0.05$; ADAS-cog improvement of 4.3 points. By comparison, a typical decline in ADAS-cog in people with AD without intervention is expected to be around 4 points over a 12-month period². All eight patients improved in a second established task, the Rey AVLT, wherein clinically important increases in word recall were present at the end of the two-month treatment period (ES=1.55; $p<0.005$) and two weeks following treatment completion (ES=1.55; $p<0.005$)

Additional results from the study find:

- TEMT also showed effects on Alzheimer's markers in blood and the cerebrospinal fluid (CSF) around the brain that were consistent with it having "disease-modifying" effects.
- TEMT appears to provide a combination of mechanisms to attack the AD process, including disaggregation of two toxic proteins (beta-amyloid and tau) that appear to be the disease's root causes – something the study's authors believe has not been seen with other AD therapeutics that are currently in clinical development.
- In individual patients, MRI brain scans also revealed signs of increased neuronal connectivity in the cingulate cortex/cingulum, an area of the brain that is involved in AD and important for integrating cognitive processes.

About the Study¹

The Pilot study was a single center, single arm trial in eight patients 63 years of age and older with mild to moderate Alzheimer's disease (AD) to evaluate the safety and initial efficacy of transcranial electromagnetic treatment (TEMT). Patients were enrolled at the University of South Florida Health/Byrd Alzheimer's Institute, which also conducted all clinical study assessments. Treatment was administered in the patient's home by a caregiver, using the MemorEM. This investigational, novel non-invasive treatment cap delivers radio waves to the brain and is designed to be easy to wear. Patients received TEMT for one-hour periods twice daily for two months for a total of 120 treatment sessions. Caregivers also monitored certain patient vitals and behaviors, such as blood pressure, body temperature, eating, drinking, movement activities and anxiety level/mood, and recorded findings in a daily diary. In addition, adverse events and suicide tendencies were assessed during clinical visits throughout the duration of the trial. Final clinical assessments were conducted two weeks after study completion. Based on the findings and the

^{*} Effect size (ES) measures the magnitude of the difference between groups or the minimal difference that is clinically important. For determination of ES, the following established scale was utilized for signifying a "clinically important" effect, based on Cohen's "d": Moderate effect (>0.5), Large effect (>0.8), Very large effect (>1.2), Huge effect (>2.0)³

positive feedback from patients, all eight were offered continued TEMT in a four-month extension study. Seven patients agreed to participate in the extension. For more information about both the completed and on-going clinical trials, visit ClinicalTrials.gov [here](#) and [here](#), respectively.

About Alzheimer's Disease⁴

Alzheimer's disease (AD) is a progressive and ultimately lethal brain disease leading to memory loss, language problems and other serious symptoms. AD is caused by the damage or destruction of brain cells (neurons) in parts of the brain that control thinking, learning and memory. Over time, people with AD increasingly become limited in performing daily activities and eventually become bed-bound, requiring care around the clock.

AD is the sixth leading cause of death in the U.S. An estimated 5.8 million Americans are living with the disease. By 2050, this number is projected to more than double to 14 million. In 2019, AD and other dementias will cost the country \$290 billion. By 2050, these costs could rise to \$1.1 trillion.

About NeuroEM Therapeutics, Inc.

NeuroEM Therapeutics is a clinical stage medical device company focused on development of Transcranial Electromagnetic Treatment (TEMT) to treat neurodegenerative disorders such as Alzheimer's Disease, Traumatic Brain Injury, and Parkinson's Disease. The company is headquartered in Phoenix, AZ and has obtained research support from the NIH, the Glass Charitable Foundation, and angel investors. NeuroEM's head device (the MemorEM) is a first-in-class medical device that provides full brain electromagnetic treatment in-home and with near complete mobility. 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.

References

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