

# NEUROHEALING

NeuroHealing Pharmaceuticals Inc.

## NeuroHealing Commences Clinical Trial Of NH001 For Coma Patients

For Immediate Release

NEWTON, Mass./EWORLDWIRE/Dec. 8, 2004 --- NeuroHealing Pharmaceuticals Inc., a private, early stage pharmaceutical company, today announced the start of a clinical trial of its first product candidate NH001 for the treatment of patients in a vegetative or minimally conscious state.

This is a multi-center, open-label, Phase IIa study to evaluate the safety and potential efficacy of NH001 in accelerating the recovery and improving the functional outcome of severe brain injured patients in a vegetative or minimally conscious state. Up to 10 adult patients will be enrolled in the study and will receive NH001 daily for up to three months. Two standard functional outcome scales, the Glasgow Outcome Scale Extended (GOS-E) and the Disability Rating Scale (DRS), will be used to follow improvement.

Patient enrollment has already begun and the first patient began treatment last week at the FLENI Hospital in Buenos Aires, Argentina by Principal Investigator Dr. Esteban Fridman. The FLENI is a well-respected, nonprofit hospital delivering preventive medicine, diagnostics and rehabilitation services for neurological medical needs. The FLENI is strongly committed to research and has participated in numerous clinical trials for multi-national pharmaceutical firms.

Each year an estimated 1.5 million people in the U.S. sustain a traumatic brain injury. As a consequence of these injuries, each year 300,000 people are hospitalized and about 85,000 people experience the onset of long-term disability. Among those hospitalized, about 50,000 to 75,000 cases result in a post-traumatic coma lasting for at least two weeks. There is no universally accepted standard of care for these patients, nor is there an approved pharmacological therapy to improve the recovery of consciousness after a traumatic brain injury.

"Post traumatic brain injury is a serious life-threatening, chronic situation. For patients in a coma beyond one month the long term prognosis for good recovery is unfortunately rather bleak," said Dr. Elkan Gamzu, chairman of the board and acting head of clinical trials for NeuroHealing. "The objective in undertaking this study is to evaluate the safety of NH001 and to observe measures of improvement in these patients in preparation for a larger double blind, placebo controlled, phase IIb study which will be conducted under an FDA IND."

"The commencement of this clinical study is an important milestone for NeuroHealing," said Neal M Farber, Ph.D., NeuroHealing's CEO. "The potential market is large and currently void of any approved products to help these patients. This patient population is concentrated in neurorehabilitation centers and skilled nursing homes which makes the market fairly easy for us to reach."

### About NH001

NH001 is a potent dopaminergic compound under development by NeuroHealing. It promotes consciousness and improves the functional outcome in patients who are currently or have previously been in a post-traumatic coma, persistent vegetative state or minimally conscious state. NH001 is expected to help patients to emerge faster from a decreased consciousness state and improve their functional recoveries. NH001 is a direct-acting dopamine agonist with strong D1- and D2-type dopamine receptor stimulating properties, and it utilizes a method of delivery that is particularly convenient for patients with consciousness disorders. NH001 has a well-established excellent safety profile in humans.

### About NeuroHealing

NeuroHealing develops and commercializes novel therapeutics based on new formulation strategies to treat the needs of post-acute neurorehabilitation patients, including disorders such as traumatic brain injury, stroke, Parkinson's disease and other motor neuron diseases.

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