US Army to conduct Phase 2 trial of Glypromate® to reduce brain injury from cardiac arrest

Key Points:

- Trial provides entry point to large market for emergency treatment of cardiac arrest and related conditions
- Glypromate® for this indication to be submitted for Orphan Drug and Fast Track designation
- Army investigators to submit IND for clinical trial approval
- Trial will give Neuren four cost-effective clinical trials in 2007

Monday 4 September 2006: Neuren Pharmaceuticals (ASX: NEU) today announced that physicians from Madigan Army Medical Center (Madigan) in Tacoma, Washington, will conduct an investigator-initiated Phase 2 trial to determine the safety and efficacy of Glypromate® in reducing brain injury caused by out of hospital cardiac arrest. The trial will start in mid-2007 and will be managed by The Henry M. Jackson Foundation for the Advancement of Military Medicine (Jackson Foundation) in consultation with the clinical investigators at Madigan.

The proposed study will be an investigator-initiated study which means that the Investigational New Drug (IND) application will be submitted to the FDA by the Army investigators rather than by Neuren. Neuren will provide the drug product as well as access to preclinical, clinical and regulatory documents related to Glypromate®. The Company's only financial commitment will be compensation to the Jackson Foundation for administrative costs incurred in coordinating the study. Neuren will retain all commercial rights to Glypromate® in these indications.

Cardiac arrest involves the sudden, complete cessation of heart function and circulation leading rapidly to neurological and other organ system damage. Among patients who survive, the consequences of neurological damage resulting from lack of blood flow and oxygen to the brain represent the primary adverse outcomes. This occurs in up to 80% of survivors and causes cognitive impairment such as occurs in patients undergoing major cardiac surgery, the focus for Neuren's upcoming Phase 3 study with Glypromate®. However recovery without residual neurological damage after cardiac arrest is rare.

There are no drugs approved to reduce the neurological damage caused by cardiac arrest. Neuren believes that Glypromate® for this indication will be eligible for Orphan Drug designation. Orphan Drug designation provides for a period of market exclusivity following approval as well as possible access to US government grants. In addition, because of the serious nature of neurological impairment resulting from cardiac arrest and the lack of available drug therapy, Neuren intends to apply for Fast Track designation which provides for accelerated clinical development and review.

While the Army's investigator-initiated trial will focus on out of hospital cardiac arrest, if this trial is successful, Neuren, the Jackson Foundation and the Army investigators are considering additional trials of Glypromate® to reduce brain damage resulting from related conditions including in-hospital cardiac arrest and treatment of patients with ventricular fibrillation, the heart rhythm disturbance associated with more than 75% of cardiac arrests.

Under the agreement, the Jackson Foundation will provide support to the Army investigators in clinical trial preparations, protocol development, obtaining human subjects clearance, coordination of patient enrolment, data management and analysis, and preparation of study reports.

Mr David Clarke, CEO of Neuren said: "This is a very important development for Neuren in that it reflects a growing appreciation of the potential for Glypromate® to reduce neurological damage. It also, of course, reinforces the value and strength of Neuren's relationship with the US Army physicians and scientists. Cardiac arrest is a devastating clinical event and one for which a drug to reduce the neurological consequences is clearly needed. The addition of this trial will now give Neuren a very strong and cost effective portfolio of clinical trials in 2007 – a Phase 3 and a Phase 2 for Glypromate® and the two Phase 2 trials with NNZ-2566."

Approximately 300,000 deaths result from cardiac arrest in the US each year, making cardiac arrest one of the leading causes of death. According to the American Heart Association, each year approximately 160,000 people in the US experience sudden cardiac arrest outside of a hospital or in a hospital emergency department.

Neuren estimates that the number of patients in the US that could be treated for out of hospital cardiac arrest and related indications is approximately 400,000 which could represent a potential market of US$800 million.

About Madigan Army Medical Center
Madigan Army Medical Center, located in Tacoma, Washington, is one of the major US Army medical centres, providing clinical care to over 120,000 active, reserve and retired military personnel and dependents. The hospital has a medical staff of more than 1,000 with 200 physicians and nurses in training. Madigan's Department of Clinical Investigations, which is dedicated to writing, performing, and regulating clinical research, is conducting approximately 200 clinical trials across a wide spectrum of indications from Phase I to IV.

About the Jackson Foundation
The Jackson Foundation is a private, not-for-profit organisation that supports the US military in conducting medical research and clinical trials and has established relationships with more than 160 military medical organisations worldwide. It was founded in 1983, in part, to foster cooperative relationships between the military medical community and the private sector, including pharmaceutical sponsors. The Jackson Foundation manages Phase I - IV clinical trials utilising an established network of military medical centres across the United States.

About Glypromate®
Glypromate® is a peptide fragment of IGF-1 and is being developed by Neuren as a potential therapeutic candidate for diseases caused by some forms of chronic or acute brain injury. Glypromate® has been shown to act by multiple pathways to protect brain tissue from injury. Neuren has successfully completed a Phase I safety study and a Phase IIa safety and pharmacokinetics study and plans to initiate a Phase III study in late 2006.

About Neuren Pharmaceuticals
Neuren Pharmaceuticals (ASX: NEU) is a biotechnology company developing novel therapeutics in the fields of brain injury and diseases and metabolic disorders. The Neuren portfolio consists of six product families, targeting markets with large unmet needs and limited competition. Neuren has three lead candidates, Glypromate® and NNZ-2566, presently in the clinic in development to treat a range of acute neurological conditions, and NNZ-2591, in preclinical development for Parkinson's and other chronic conditions. Neuren has commercial and development partnerships with the US Army Walter Reed Army Institute of Research, Metabolic Pharmaceuticals, UCLA Medical Center and the National Trauma Research Institute in Melbourne.

For more information, please visit Neuren's website at www.neurenpharma.com

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