First Patient Enters Phase 3 Glypromate® Trial

Key Points:

- **First patient enters Phase 3 trial in the US**
- **Systems and logistics function successfully**
- **Adaptive design of trial reduces risk**

Thursday 31 May 2007: Neuren Pharmaceuticals Ltd (ASX:NEU) today announced that the first patient has entered the Phase 3 clinical trial of its lead compound, Glypromate®, to reduce cognitive impairment in patients following cardiac surgery. The first patient was dosed at the Lindner Center in Cincinnati, Ohio, US. The Phase 3 trial represents a key milestone for Neuren as it progresses Glypromate® towards commercialisation.

Almost 70 per cent of patients who have cardiac surgery with cardiopulmonary bypass experience cognitive decline at discharge and up to 35 per cent of patients' exhibit cognitive impairment three months after the operation. With nearly one million procedures performed annually in the US and other developed markets, more than 200,000 patients per year are left with persistent cognitive impairment. The goal of the trial is to reduce the level of cognitive decline and associated functional problems experienced by these patients.

During cardiac surgery with bypass, the patient's heart is stopped and the blood flow is directed through a device called a heart lung machine that oxygenates the blood and pumps it through the body while the heart is stopped. During this time the aorta, the artery which normally carries oxygenated blood from the heart, is clamped shut. Many experts in this area believe that the small particles of fat and other material, called microemboli, released when the aorta is unclamped at the end of bypass are a primary cause of the brain damage that causes cognitive impairment. During the trial, Glypromate® will be administered as a 4-hour infusion beginning shortly after the heart is restarted and the aorta is unclamped. Neuren believes that starting the infusion just at the point where brain damage is believed to occur will maximise the opportunity for the drug to protect the brain.

There are currently no drugs approved to reduce cognitive impairment following cardiac surgery, representing a market potential estimated at more than US$1 billion and an opportunity for Neuren's Glypromate®, once approved, to be the first available in the market.

The trial will involve approximately 600 patients across 24 sites in the United States, Australia and New Zealand. Clinical sites in Atlanta, Charleston and other US sites are expected to begin enrolling patients shortly, with enrolment expected to be completed by the end of 2008.

The majority of patients will be enrolled at sites in Australia and New Zealand, where Neuren will be monitoring and managing the double-blind, multi-centre, placebo-controlled trial. Change in cognitive function from before surgery to three months after surgery is a primary endpoint of the study and will be assessed using computerised software that combines 15 different standardised and well-validated tests to measure eight separate aspects of cognitive function called domains. Use of a score that measures change, and where each patient serves as his or her own control, has enabled Neuren to design a highly cost-effective study.

The US Food and Drug Administration (FDA) has allowed a review of data on the primary endpoints after 300 patients have been enrolled without un-blinding the study to evaluate variance and possibly increase the number of patients. This adaptive trial design is an important element of the FDA agreed study design as it reduces the risk of a negative outcome that could result from higher than expected variation in the test results independent of the effects of the drug.

David Clarke, Neuren's CEO, commented: "This is a major milestone for Neuren. It represents the culmination of a long and challenging development process that required a great deal of effort and commitment on the part of our staff and consultants. It also represents the beginning of the process through which Neuren will come to be recognised by its peers as a serious player in the global biotechnology industry."

About Neuren Pharmaceuticals

Neuren Pharmaceuticals (ASX: NEU) is a biopharmaceutical 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 clinical trials 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, including with the U.S. 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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Clinical Appendix

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Trial Title: A Randomised, Double-blind, Placebo-controlled Study of Glypromate® in Patients Undergoing Cardiopulmonary Bypass Surgery

Trial Objective: To evaluate the efficacy of Glypromate® compared to placebo in the reduction of cognitive decline and comparative levels in functional activities of daily living in patients undergoing coronary artery bypass graft (CABG) surgery and/or valve replacement/repair with cardiopulmonary bypass surgery (CPB).

Primary Endpoints: A change from baseline in the composite cognitive score and the comparative levels in the activities of daily living composite score are co-primary efficacy outcome variables.

Secondary Endpoints:

- Global evaluation of patient's activities of daily living, Q 101 of the OARS Multidimensional Functional Assessment Questionnaire.
- The effect of Glypromate® compared to placebo on the incidence of stroke and transient ischaemic attack after CABG surgery and/or valve replacement/repair with CBL.
- The effect of Glypromate® compared to placebo following CABG surgery and/or valve replacement/repair with CPB surgery on the change in domain and individual cognitive test performance.

Safety: The safety objective is to evaluate the effect of Glypromate® compared to placebo following CPB surgery on the incidence of adverse events up to the 12-14 week follow-up.

Method: Approximately 600 cardiac surgery patients (males and females >50 years) will receive 1 mg/kg/hr infusion of Glypromate or placebo for 4 hours beginning at the end of surgery.