Neuren launches Australian Phase 3 Trial Sites

Key points:

- **First patient enters Phase 3 trial in Australia to reduce cognitive decline following cardiac surgery**
- **Cognitive decline affects 70% of patients undergoing heart bypass surgery**

Wednesday 26 September 2007: Neuren Pharmaceuticals Limited (ASX:NEU) today announced that the first Australian patient has entered the Phase 3 clinical trial of its lead compound Glypromate®, in development to reduce cognitive impairment after cardiac surgery.

Glypromate® is currently undergoing Phase 3 clinical trials in Australia, the United States and New Zealand. Two hundred and fifty patients, out of a total of approximately 600, will undergo treatment in 13 Australian sites across Sydney, Adelaide, Perth, Brisbane and Melbourne. The first Australian patient was dosed at the Flinders Medical Centre in Adelaide this week. The trial is expected to last 18 months, with recruitment completed by the end of 2008. All patients will be over 50 years old and scheduled for cardiac bypass graft (CABG) surgery due to blocked arteries that are vital for supplying the blood to the heart, or valve replacement surgery, under heart bypass. Fourteen patients have already received treatment in the US and New Zealand.

Professor John Knight, Cardiac Surgeon and Australian Principal Investigator at the Flinders Medical Centre said, “We are very excited to launch the Australian arm of this ground-breaking Phase 3 trial. Cognitive impairment can be a debilitating condition in a lot of cases.”

With cardiac surgery reaching up to 1.25 million procedures per year, worldwide costs have increased to around US$50 billion annually. More than 70 percent of patients that undergo cardiac surgery experience cognitive impairment (brain damage) following the surgery. Small fragments, known as emboli, being dislodged from blood vessels during the bypass procedure causing disruptions in blood supply to the brain, have been identified to be the cause of cognitive impairment in cardiac patients. These conclusions may also be linked closely to the brain damage in patients who experience a stroke and heart attack, which is also caused by disruptions in blood supply.

There is currently no treatment available to prevent this damage.

A new drug, Glypromate®, is being developed by Neuren as a potential therapeutic candidate to reduce cognitive decline in patients following cardiac surgery. Glypromate® works by surrounding the two major classes of cells in the brain, neurons and the cells surrounding neurons. This significantly reduces cell death and decreases the inflammatory response caused by the procedure to protect the patient from cognitive impairment.

To provide medical oversight for the study, Neuren has formed an Executive Committee comprising a number of global leading clinicians and researchers in neurology, cardiology, cardiothoracic surgery and anaesthesiology. The members of the Executive Committee are Professor Harvey White (Auckland Hospital, Professor of Cardiology, Chair), Professor Alan Merry (Auckland Hospital, Professor of Anaesthetics), Professor John Knight (Flinders

Medical Centre, Australia, Cardiac Surgeon), Dr David Stump (Wake Forest, USA, Anaesthetist), Dr John Hammon (Wake Forest, USA, Cardiac Surgeon), Dr Doug Wilson (Neuren's Chief Medical Officer) and Dr Keith Wesnes (Cognitive Drug Research, UK, Neuropsychologist).

The US Food and Drug Administration (FDA) accepted Neuren's Investigational New Drug (IND) application for Glypromate® earlier this year. The trial design is in accordance with FDA guidelines and the results will support the future registration of Glypromate® in the United States and other global markets.

Clinical Appendix

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

Protocol Abbreviated Name: Studying **N**eurons **U**sing **G**lypromate® **2 (SNUG-2)**

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 CPB.
- 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 intravenous infusion of Glypromate® or placebo for 4 hours beginning at the end of surgery. The study will be performed in accordance with ICH GCP and all applicable local regulations.

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

About Glypromate®

During cardiac surgery with bypass, the patient's heart is stopped and the blood flow is directed through a device called a heart lung bypass 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 leads to cognitive impairment. After the surgery when the heart has been restarted, Glypromate® is administered. Glypromate® then protects the two major classes of cells in the brain, significantly reducing cell death. It also decreases the inflammatory response caused by the injury.

About Cognitive Impairment in Cardiac Surgery

Damage to the brain most commonly occurs as a result of small fragments known as emboli being dislodged from blood vessels during the bypass procedure and travelling to the brain, where they result in 'mini-strokes'.

With cardiac surgery reaching up to 1.25 million procedures per year worldwide costs have increased to around US$50 billion annually.[1] Coronary artery disease (CAD) is the most common type of heart disease globally and is a serious health problem worldwide. CAD causes approximately 17 million deaths per year: the equivalent of one out of every three deaths worldwide.[2] There is currently no treatment available to address the damage caused by these emboli.

Contact details:

Neuren	**Media and investor relations**
David Clarke CEO T: 1 800 259 181 (Australia) T: +64 9 529 3942 (NZ) M: +64 21 988 052	Rebecca Piercy Buchan Consulting T: +61 2 9237 2800 M: +61 422 916 422

[1] www.bloodcoagulation.com

[2] http://money.cnn.com/news/newsfeeds/articles/prnewswire/UKSU00802092007-1.htm