



Neuren launches NZ arm of Global Phase 3 Trial

Friday 7 September 2007: The New Zealand biotech sector has moved into a new stage of development with the recruitment of New Zealand patients into a Phase 3 trial of a locally developed drug by Neuren Pharmaceuticals Limited (ASX: NEU).

Neuren has launched the New Zealand arm of its Phase 3 trial of Glypromate[®], one of the first compounds developed in New Zealand by a New Zealand company to enter a global Phase 3 clinical trial.

Glypromate[®] has been developed to protect brain function, the loss of which is a common side-effect of cardiac surgery. Approximately 70% of patients who have cardiac surgery with cardiopulmonary bypass experience a cognitive decline and half of these will still exhibit impairment three months later.

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 nearly one million cardiac surgery procedures performed annually in the United States and other developed countries, including approximately 800,000 coronary artery bypass grafts and 200,000 valve repairs or replacements using cardiopulmonary bypass, as many as 350,000 patients per year are left with persistent cognitive impairment in the United States alone. There is currently no treatment available to address the damage caused by these emboli.

Following its successful filing of an investigational new drug application (IND) earlier this year, Neuren was given the go-ahead to begin the Phase 3 trial. The IND application and subsequent discussions were important steps towards ensuring that the trial will be conducted in accordance with FDA guidelines and that the results from the study will support the registration of Glypromate[®] in the United States and other global markets.

The Phase 3 trial will be a double-blind placebo controlled trial with approximately 600 patients in Australia, New Zealand and the United States participating. The United States arm of the trial commenced in May. Patients undergo a computerised test of cognitive functions, such as memory and attention, prior to and after surgery to assess how successful Glypromate[®] has been at protecting the brain during cardiac surgery.

Patient recruitment has already started in New Zealand. It is planned that 200 New Zealand patients will take part in the trial which is being undertaken in Auckland at Auckland Hospital and Mercy Hospital; in Hamilton at Waikato Hospital; in Wellington at Wakefield Hospital, and in Christchurch at Christchurch Hospital and St George Hospital.

Patients being recruited into the trial must be scheduled for cardiac bypass graft (CABG) surgery or valve replacement surgery with cardiopulmonary bypass, and they must be over the age of 50. It is anticipated that the trial will take 18 months to complete with final data from the trial available in mid-2009.



The Australian sites in the trial have already been initiated and recruitment is expected to start in Australia within the next three weeks.

Neuren CEO David Clarke said “We are very pleased to launch the New Zealand arm of this exciting and ground-breaking Phase 3 trial. If the results of this trial are positive, we will conduct one further Phase 3 trial and then seek to register Glypromate® with the FDA and other regulators around the world for commercial use.”

Clinical trials

- A Phase 1 study involves a trial of a product on healthy individuals to test the safety of the drug
- A Phase 2 study is a trial on individuals who have the targeted disease or condition, to further test the safety and establish the initial efficacy of the product
- A Phase 3 study is a larger trial for patients in the target population to further prove the efficacy of the product.

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).

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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