Neuren clinical development program update

- Company poised for multiple late stage patient trials by mid-2008 -

Tuesday 4 December 2007: Neuren Pharmaceuticals (ASX: NEU) today announced that it is on track to have four Phase 2 or Phase 3 clinical trials in progress in four different indications by the middle of next year. As a result, the Company will have one of the most advanced and comprehensive late stage drug pipelines in Australasia.

The most advanced product in Neuren's pipeline is Glypromate® which is in a Phase 3 trial for the reduction of cognitive impairment in patients undergoing cardiac surgery. The trial is well underway with recruitment taking place in four Australian sites and eleven sites in New Zealand and the US.

Phase 1a and 1b safety trials have been completed for Neuren's second lead compound, NNZ-2566, and the Company is planning to file an Investigational New Drug (IND) application with the US FDA in early 2008 and to initiate two Phase 2 trials in collaboration with the US Army. Motiva™, the third compound in the product pipeline, already has an open IND with the US FDA and preparations are underway for a Phase 2b trial.

Glypromate® Phase 3 trial

Key points:

- US, New Zealand and Australian trial sites now recruiting
- Patient recruitment and safety on track
- Phase 3 trial estimated to finish recruiting in December 2008

Glypromate® is being evaluated to reduce cognitive impairment which occurs in up to 70 percent of patients who undergo cardiac surgery with cardiopulmonary bypass. If proven successful in this indication, the drug could also be tested in heart attack and stroke patients.

Neuren successfully filed an IND earlier this year, and the Phase 3 trial is now recruiting patients at 15 of the 24 sites involved in the study, including all of the New Zealand and the US sites.

The remaining 9 sites in Australia will commence recruitment over the next 1-2 weeks.

Glypromate® Phase 3 Trial

Aim:
Reduce cognitive impairment in cardiac surgery patients

Endpoint(s):
Cognitive function, ADL, safety

Patients:
600 cardiac surgery patients, males & females > 50 years

Dose:
1 mg/kg/hr infusion for 4 hours

Design:
Randomised, single dose, double-blind, placebo controlled, two equal arms

To date, the Company has recruited 66 patients out of the expected 600 to complete the trial. This is in line with the planned trial site commencements and the trial's objective of completing enrolment by December 2008. Results of the trial are expected to be released in mid-2009.

Previously completed Phase 1 and 2a trials confirmed the drug's safety in healthy volunteers and cardiac surgery patients. The Data Safety Monitoring Committee (DSMC) will review patient data after 100 patients in the first quarter of 2008 and again at 300 patients in the third quarter. The reviews will involve a comprehensive safety assessment without unblinding the data. The Company also will determine statistical variance of the endpoints on unblinded data to validate that the targeted sample size is appropriate.

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).

Motiva™ (nefiracetam) clinical trial

Key Points:

- Motiva™ has proven efficacy in 7 clinical trials
- US IND is open
- Preparations are underway for a Phase 2b trial
- Trial is scheduled to start in mid-2008 in the US

Motiva™, a compound that was recently acquired by Neuren through the acquisition of Hamilton Pharmaceuticals, is being developed as a therapy for neuropsychiatric complications of stroke which lends itself well to Neuren's primary focus on cognitive and psychiatric consequences of brain injury.

The drug has been tested in patients with a recent stroke in seven Phase 2 and 3 clinical trials in Japan, the US and Canada. Motiva™ has exhibited good safety and efficacy in this patient population.

Motiva™ Phase 2b Trial

Aim:
Confirm the efficacy of Motiva™ in patients with post-stroke neuropsychiatric sequelae

Endpoints:
Improvement of apathy symptoms, depression, cognitive function and functional independence

Patients:
120 patients who have had a cortical stroke, and are suffering from post-stroke depression and apathy

Neuren is currently designing a Phase 2b trial which will address post-stroke depression, apathy, cognitive impairment and functional independence. The US IND for Motiva™ is open and, after submission of the completed protocol to the FDA, the Phase 2 trial will commence in the US by mid-2008. The trial is expected to be completed in 2009. The trial will incorporate a higher dosing regime, broader range of cognitive and neuropsychiatric endpoints and more stringent patient selection criteria than previous trials to enhance the likelihood of success in subsequent registration trials.

NNZ-2566 clinical trials

Key points:

- Phase 1a and 1b studies completed with favourable safety findings
- Drug manufacturing completed
- IND and study preparations for both mild-moderate and severe traumatic brain injury studies well underway
- Lead sites identified
- Confirmation of US Army funding for both protocols expected in December 2007

Neuren and the US Army are initiating two clinical trials with NNZ-2566, a Phase 2a trial targeting severe traumatic brain injury (TBI) and a Phase 2 trial targeting mild-to-moderate TBI. These are planned to run concurrently.

Phase 2 - Mild-to-moderate TBI

The first Phase 2 study in mild-to-moderate TBI patients will be conducted under a US IND. Given the timelines for IND filing, the trial will be initiated in mid-2008. It will involve 150 patients and will run for approximately 18 months.

The primary endpoints in the study will be neuropsychological and neurocognitive function. Depression, short term memory loss and attention deficit are frequent consequences of mild-to-moderate TBI and can cause significant disability. Neuren also plans to incorporate a number of biomarkers in this trial to determine the effect of the drug in reducing brain damage. These will be provided by Banyan Biomarkers, a spin-out from the McKnight Brain Institute at the University of Florida. Banyan has shown strong correlation between the level of these biomarkers and severity of injury in human clinical trials funded by the US Army.

Dr Jeffrey Bazarian, Associate Professor of Emergency Medicine and Neurology from the University of Rochester (New York) and a leader in mild-moderate TBI research, will be the lead PI for the mild-moderate TBI protocol. This protocol is now complete, and ready for filing with the FDA for a pre-IND meeting to be held in early 2008.

NNZ-2566 Mild-Moderate TBI Trial

Aim:
Determine safety and efficacy of NNZ-2566 in mild-moderate TBI patients

Endpoint(s):
Cognitive function, mood and psychological function, ADL, safety

Patients:
150 patients who have had a head injury with a GCS (Glasgow Coma Score) of 9-15 and evidence of injury on CT scan

Dose:
20mg/kg bolus followed by infusion of 6 mg/kg/hr for 24 hours

Design:
Randomised, double blind, single dose, placebo controlled trial

Phase 2a - Severe TBI

The funding of this trial by the US Army is expected to be confirmed shortly. Neuren has begun development of an IND package for NNZ-2566 and plans to hold a pre-IND meeting with the US FDA in early 2008 to seek agreement on protocol design and clinical endpoints. This will support initiation of a Phase 2a trial in the US which is planned to start in mid-2008.

In addition to mortality, haemodynamic status and neurological function, the trial will incorporate biochemical and electroencephalographic markers. The Phase 2a study will run for approximately one year and will involve 100 patients. If results from the Phase 2a are positive, Neuren and the US Army plan to start a pivotal Phase 2b efficacy study in early 2010.

Neuren has established an Advisory Committee to guide TBI clinical trial design and execution. The committee comprises internationally recognised neurosurgeons, neurologists and neuropsychologists from both the US Army and leading civilian institutions in the US.

NNZ-2566 Severe TBI Trial

Aim:
Determine safety and efficacy of NNZ-2566 in severe TBI patients

Endpoints:
Mortality, neurological function, non-convulsive seizures

Patients:
100 patients who have had a head injury with a GCS (Glasgow Coma Score) of 3-8

Dose:
20mg/kg bolus followed by infusion of 6 mg/kg/hr for 24 hours

Design:
Randomised, double blind, single dose, placebo controlled trial

Dr Ross Bullock, Chief of The Neuroscience Critical Care at the University of Miami (Florida) will be the lead PI on the severe TBI trials. He has conducted more than 15 severe TBI trials in the past and is the co-author on the definitive text on head injury. Neuren is working closely with Dr Bullock and other members of the Advisory Committee to finalise the severe TBI protocol.

Terminology:

ADL = Activities of daily living
Bolus = single injection
IV = intravenous (into the vein)
GMP = Good Manufacturing Practice (required drug manufacturing standard for human use)
FDA = Food and Drug Administration (USA regulatory body)
IND = Investigational New Drug application (an application to the FDA to conduct human trials)

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 eight product families, targeting markets with large unmet needs and limited competition. Neuren has four lead candidates, Glypromate®, Motiva™, NNZ-2566 and NNZ-2591 targeting a range of acute and chronic neurological conditions.

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

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