Clinical Trials Update

Key Points:

Glypromate®

- U.S. sites for Glypromate® Phase 3 trial to be initiated this month
- All sites selected and all drug manufacture completed for Phase 3 trial
- All management and logistical resources in place for the Phase 3 trial
- Phase 3 trial estimated to take 18 months

NNZ-2566

- Single Phase 1b design enabling both Phase 2 trials. Phase 1b to complete in Q307
- Protocol for Phase 2 trials in Australia (starting Q407) and U.S. (starting Q108) on track
- Both Phase 2 studies are expected to take 12-15 months

Thursday 10 May 2007: Neuren Pharmaceuticals (ASX: NEU) today announced details on the status of its lead compounds, Glypromate® and NNZ-2566. Following is a summary of the current status of the trials. Neuren will provide further updates as the trials progress.

Glypromate® Phase 3 Trial

Following its successful filing of an investigational new drug application (IND) earlier this year, Neuren has been in technical discussions with the U.S. Food and Drug Administration (FDA) to finalise the detailed trial design. Neuren will now start the Phase 3 trial in May following a modified protocol based on those discussions. In particular, it has been confirmed that the efficacy measure of cognitive impairment being used is a well-recognised and accepted endpoint. It comprises a series of standardised assessments in a validated, computerised system developed by Cognitive Drug Research Ltd (UK) and has been used in a large number of FDA trials. Cognitive impairment is commonly used as an endpoint in many trials including stroke, cardiac surgery, traumatic brain injury, Alzheimer's disease and Schizophrenia. The trial also will evaluate effects on activities of daily living (ADL).

Glypromate®

Aim:
Reduce cognitive impairment in cardiac surgery patients

Endpoint(s):
Cognitive function, ADLs, safety

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

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

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

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 U.S. The development of infrastructure and planning required for this trial has been significant. The FDA submission itself was over 2500 pages long and each site has been individually visited and audited.

The Phase 3 trial will be a double blind placebo controlled trial with 600 patients. It will start in May 2007 at the Lindner Center in Cincinnati, Ohio which has obtained preliminary ethics approval. It will continue for approximately 18 months in various sites in the USA, Australia and New Zealand.

The approved trial sites to date are:

U.S. Sites

1. Jackson Hall Medical Center –Tacoma, WA
2. Wake Forest University – Winston-Salem, NC
3. Madigan Army Medical Center – Tacoma, WA
4. Lindner Center – Cincinnati, OH
5. Union Memorial Hospital – Baltimore, MD
6. CAMC Health Education & Research Institute – Charleston, WV
7. Atlanta Heart & Vascular Institute – Atlanta, GA

Australian Sites

1. Flinders Medical Centre – Adelaide
2. Ashford Hospital – Adelaide
3. Princess Alexandra – Brisbane
4. Alfred Hospital – Melbourne
5. St. Vincent's Hospital – Melbourne
6. Royal Perth Hospital – Perth
7. Sir Charles Gardner – Perth
8. Royal Prince Alfred – Sydney
9. Prince of Wales – Sydney
10. St Vincent's Hospital – Sydney
11. Liverpool Hospital - Sydney

New Zealand Sites

1. Auckland City Hospital
2. Mercy Hospital – Auckland
3. Waikato Hospital – Hamilton
4. Wakefield Hospital – Wellington
5. Christchurch Hospital – Christchurch
6. St George Hospital – Christchurch

In preparation for the study, Neuren has retained Hesperion, a Basel-based Contract Research Organisation with major operations in the USA, as the global manager for the trial. Hesperion is a leading provider of clinical trial management services for studies in cardiovascular indications. Neuren has also increased its own internal resources and the Neuren clinical trials team now has over 36 years of experience running large global Phase 2 and 3 trials.

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

NNZ-2566 clinical trials

As previously announced, Neuren and the U.S. Army are planning two sets of clinical trials of NNZ-2566, one for severe traumatic brain injury (TBI) and one for mild-to-moderate TBI. A Phase 1a safety study comprising a single bolus injection has been successfully completed. To date the drug has been shown to be safe and well tolerated. A Phase 1b trial involving a single bolus injection followed by an infusion is underway. This trial has been designed to combine Phase 1 requirements for both severe and mild-to-moderate TBI and to allow significant flexibility in the design of Phase 2 trials for both of these indications. Although this has involved greater up front costs, especially in the case of severe TBI which requires high doses of the drug, the long-term benefit to Neuren will also be significant. The Phase 1b trial is planned for completion September 2007.

NNZ-2566

Aim:
Determine safety, tolerability and pharmacokinetic (PK)

Patients:
Normal, healthy volunteers

Doses:
Phase 1a—up to 20 mg/kg
Phase 1b—up to 20mg iv/kg bolus followed by 9 mg/kg/hr iv for 72 hours. 4 cohorts (5 drug: 2 control)

Design:
Randomised, double blind, single dose, multiple cohort, dose escalation

Phase 2 - Mild-to-moderate TBI

The first Phase 2 study in mild-to-moderate TBI patients is expected to start in the second half of this year in Australia and New Zealand. It will involve 60-70 patients and will run for approximately 15 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 U.S. Army.

Phase 2a - Severe TBI

Neuren has begun development of an IND package for NNZ-2566 for this indication and plans to hold a pre-IND meeting with the U.S. FDA later in the year to seek agreement on protocol design and clinical endpoints. This will support initiation of a Phase 2a trial in the U.S. which is planned to start in Q1 2008. In addition to mortality and neurological function, the trial will incorporate biochemical and electroencephalographic markers. The Phase 2a study will run for approximately one year and will involve 40-50 patients. If results from the Phase 2a are positive, Neuren and the U.S. Army plan to start a pivotal Phase 2b efficacy study in the second half of 2008

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 U.S. Army and leading civilian institutions in the U.S., Australia and Europe.

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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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)
PK = Pharmacokinetics (level of drug in the blood and rate of drug elimination)