

## Neuren initiates Phase 2 trial

**Tuesday 30 August 2005:** Neuren Pharmaceuticals (ASX: NEU) announced today it has initiated its Phase 2 pharmacokinetics and safety trial of its lead drug Glypromate<sup>®</sup>.

Recruitment has begun for the 30 patients involved in the trial, which is scheduled for completion at the end of 2005.

The trial will take place at multiple sites namely Auckland City Hospital, the Mercy Ascot Hospital, Waikato Hospital and Wakefield Hospital in New Zealand and at the Alfred Hospital in Australia in preparation for the larger Phase 3 trial next year.

"This is an exciting opportunity for Australasian researchers to be involved in early development with such a novel compound" said Robyn Murdoch, Chief Development Officer of Neuren.

The trial is aimed at confirming the pharmacokinetic profile and safety of Glypromate<sup>®</sup> ahead of a Phase 3 trial that will assess the effectiveness of the compound as a protection from neurocognitive disturbance following coronary artery bypass graft surgery (CABG). Impaired cognition is a known complication of CABG.

As announced in June 2005, once the Phase 2 trial is successfully completed and other Phase 3 prerequisites finalised, Neuren will file with the US Food and Drug Administration (FDA) to proceed directly to a Phase 3 major efficacy study, thereby avoiding a Phase 2b trial. This will mean that not only will Neuren save the cost of the Phase 2b trial, estimated at AUD\$6-8 million, but it will allow Neuren to progress to Phase 3 in 2006 rather than 2008.

"This represents another key milestone for the Company and also illustrates the progress we are making towards Phase 3 and eventual commercialisation of Glypromate<sup>®</sup>. Phase 3 is expected to begin in mid-2006" said Mr David Clarke, Chief Executive Officer of Neuren.

"We have put considerable effort and time into using multiple sites for this trial in preparation for Phase 3 next year," Mr Clarke added.

Over 400,000 patients undergo CABG surgery each year in the US and some loss of brain function has been reported in up to 70% of patients at discharge. The target market for CABG is estimated at USD\$2 billion worldwide and the target market for similar related diseases, such as Stroke and Traumatic Brain Injury is estimated at USD\$4.5 billion worldwide.

## About Glypromate<sup>®</sup>

Glypromate<sup>®</sup> is a naturally occurring peptide fragment that is found in normal brain tissue. When injected intravenously, Glypromate<sup>®</sup> has been shown to act by multiple pathways in protecting brain tissue from injury. Glypromate<sup>®</sup> is a potential therapeutic candidate for diseases caused by some form of chronic or acute brain injury.

## **About Neuren Pharmaceuticals**

Neuren Pharmaceuticals (ASX: NEU) is a biotechnology company developing novel therapeutics in the fields of neuroprotection and metabolic disorders. The Neuren portfolio consists of five product families, targeting markets with large unmet needs and limited competition. Neuren has two lead candidates, Glypromate<sup>®</sup> and NNZ-2566, targeting a range of acute neurological conditions. Neuren has commercial and development partnerships, including with Pfizer, the US Army's Walter Reed Army Institute of Research and Metabolic Pharmaceuticals.

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

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