



## **Neuren's second lead compound to commence Phase 1 trial**

**Monday 6 March 2006:** Neuren Pharmaceuticals Ltd (ASX:NEU) has received all necessary regulatory approvals and will commence a Phase 1 trial of its second drug, NNZ-2566, for the treatment of traumatic brain injury (TBI). The trial will be carried out in healthy volunteers at the Royal Alfred Hospital in Melbourne.

NNZ-2566 is being developed by Neuren for the treatment of TBI and other acute and chronic neurological conditions. A Phase 1 trial is the first "in man" clinical trial to assess the initial safety of a drug in humans. The trial will involve 35 healthy volunteers and expected to be completed by the third quarter of calendar year 2006.

Neuren's TBI program is being implemented in collaboration with the US Army's Walter Reed Army Institute of Research (WRAIR) pursuant to a cooperative research and development agreement. Under the agreement WRAIR evaluated the efficacy of the drug in reducing the neurological consequences of brain injury in experimental models.

To date, research conducted by Neuren and WRAIR has shown that NNZ-2566 provides substantial benefits in several different models of brain injury. The research has produced three scientific abstracts; one was presented in August 2005 and two have been submitted for presentation later this year.

In preclinical safety studies conducted as prerequisites for the Phase 1 study, NNZ-2566 has proven to be safe and without toxicity in both rats and dogs at doses up to more than 20 times the highest daily dose planned for the Phase 1 study. Neuren is also planning a second stage of the Phase 1 study to confirm safety and evaluate pharmacokinetics with longer infusion times.

These two studies will provide maximum flexibility in determining the optimal dose and duration of therapy in subsequent clinical trials in patients. Neuren believes that the drug's safety profile will permit dosing at levels sufficient to achieve the best possible therapeutic effect. Previous studies in TBI have been significantly hampered by dose-related toxicity and the consequent limitations in dosing. This study design will also afford Neuren a wider range of potential future target conditions in addition to TBI.

Mr David Clarke said: "This is an exciting milestone both for NNZ-2566, and the company. With two compounds in clinical trials, this clearly reflects the continuing success of Neuren's programs and the robustness of our pipeline. The first drug, Glypromate<sup>®</sup> is in a Phase 2 study in cardiac surgery patients. NNZ-2566 is also available in an oral form making it applicable to a wide range of acute and chronic diseases."

### **About Walter Reed Army Institute of Research**

Walter Reed is the largest, most diverse, and oldest laboratory in the US Army Medical Research and Material Command. It conducts research on a range of military relevant issues, including naturally occurring infectious diseases, combat casualty care, operational health hazards, and medical defence against biological and chemical weapons. Walter Reed is the Department of Defense's lead agency for infectious disease research and a crucial source of research support for medical product development.



**About Neuren Pharmaceuticals**

Neuren Pharmaceuticals (ASX: NEU) is a biotechnology company developing novel therapeutics in the fields of neurotherapy and metabolic disorders. The Neuren portfolio consists of six 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 and chronic neurological conditions. Neuren has commercial and development partnerships, including 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](http://www.neurenpharma.com)

**Contact details**

<b>Company</b>	<b>Media and investor relations</b>
David Clarke CEO T: 1800 259 181 (Australia) T: +64 9 367 7167 ext 82308 (NZ) M: +64 21 988 052	Rebecca Piercy Buchan Consulting T: +61 2 9237 2800 M: +61 422 916 422