



## **Glypromate<sup>®</sup> trial recruits 100<sup>th</sup> patient**

### **Key Points:**

- **Glypromate<sup>®</sup> SNUG-2 trial reaches 100<sup>th</sup> randomised patient milestone**
- **The trial is on track to recruit 600 patients by the end of 2008**

**Thursday, 17 January 2008:** Neuren Pharmaceuticals (ASX:NEU) today announced that its Phase III clinical trial with lead compound Glypromate<sup>®</sup>, in development to reduce cognitive impairment following cardiac surgery, has recruited its 100<sup>th</sup> patient. This is in line with the trial's objective of completing enrolment by December 2008, as almost all sites are now recruiting.

The Data Safety Monitoring Committee (DSMC) will review the patient data of these 100 patients and again at 300 patients in mid-2008. The reviews will involve a comprehensive safety assessment without unblinding the data. Neuren will also determine statistical variance of the endpoints on unblinded data to validate that the targeted sample size is appropriate.

Dr Parmjot Bains, Co-CEO (Australasia) said: "We are very pleased to have achieved this major recruitment milestone. Recruitment for the trial is well on track to achieving the targeted 600 completed patients. All sites are now active in the US and New Zealand."

To date, six sites are currently underway in Australia and another six sites will be initiated in early February 2008.

Glypromate<sup>®</sup> is being developed to treat cognitive impairment (brain injury) which occurs in 70 percent of patients that undergo cardiac bypass surgery. If proven successful, the compound may also be applied to sufferers of heart attack and stroke.

## **Clinical Appendix**

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**Trial Title:** A Randomised, Double-blind, Placebo-controlled Study of Glypromate<sup>®</sup> in Patients Undergoing Cardiopulmonary Bypass Surgery

**Protocol Abbreviated Name:** Studying Neurons Using Glypromate<sup>®</sup> 2 (SNUG-2)

**Trial Objective:** To evaluate the efficacy of Glypromate<sup>®</sup> compared to placebo in the reduction of cognitive decline and comparative levels in functional activities of daily living in patients undergoing coronary artery bypass graft (CABG) surgery and/or valve replacement/repair, with cardiopulmonary bypass surgery (CPB).

**Primary Endpoints:** A change from baseline in the composite cognitive score and the comparative levels in the activities of daily living composite score are co-primary efficacy outcome variables.

**Secondary Endpoints:**

- Global evaluation of patient's activities of daily living, Q 101 of the OARS Multidimensional Functional Assessment Questionnaire.
- The effect of Glypromate<sup>®</sup> compared to placebo on the incidence of stroke and transient ischaemic attack after CABG surgery and/or valve replacement/repair with CPB.
- The effect of Glypromate<sup>®</sup> compared to placebo following CABG surgery and/or valve replacement/repair, with CPB surgery, on the change in domain and individual cognitive test performance.

**Safety:** The safety objective is to evaluate the effect of Glypromate<sup>®</sup> compared to placebo following CPB surgery on the incidence of adverse events up to the 12-14 week follow-up.

**Method:** Approximately 600 cardiac surgery patients (males and females >50 years) will receive 1 mg/kg/hr intravenous infusion of Glypromate<sup>®</sup> or placebo for 4 hours beginning at the end of surgery. The study will be performed in accordance with ICH GCP and all applicable local regulations.

**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<sup>®</sup>, Motiva<sup>™</sup>, 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](http://www.neurenpharma.com).

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