

## US Food and Drug Administration (FDA) advances Neuren to Phase 3 next year

### Key points:

- Significant cost savings for Neuren
- Positions Neuren as one of very few ASX-listed companies poised to enter Phase 3
- Reduces time to market for the drug
- Increases potential to out-license and generate nearer term revenue

**6 June 2005:** Neuren Pharmaceutical's (ASX:NEU) clinical trial program for its lead drug Glypromate® has been significantly shortened following a recent pre-investigational new drug (IND) meeting with the US Food and Drug Administration (FDA) in Washington DC. The company will now proceed directly to a major efficacy study (Phase 3), after completion of a small Phase 2a trial, involving 30 patients, scheduled for completion at the end of 2005 and other standard pre-requisites for Phase 3.

This means the cost of the previously planned Phase 2b study, estimated at AUD\$6 million, can be avoided. It also means that the Phase 3 study can begin in 2006, rather than 2008, and could be completed without necessarily having to out-license or partner.

Although generally more rigorous, the Phase 3 trial will be based on the previously planned 2b trial and will involve a similar number of patients, between 400 and 500 people. It will cost significantly less than many trials at this stage, and is expected to be in the order of the Phase 2b trial.

The move will make Neuren one of only a few companies listed in Australia with a drug poised to enter Phase 3 at a very modest cost for Phase 3 trials.

"This is a major business opportunity for Neuren on a number of levels. Our Phase 3 trial program is not only advanced to 2006, but the overall drug development program should now cost many millions of dollars less because of this decision. On top of this, our potential to out-license and generate nearer-term revenue is increased substantially," said Mr David Clarke, Chief Executive Officer of Neuren.

"This outcome of the FDA meeting for Glypromate® and Neuren creates a unique opportunity for us that is very unusual for a biotech company. The FDA recognises there are currently no treatments to prevent the loss of brain function following coronary artery bypass grafting surgery (CABG) and we will be working with the FDA to refine the final design of the new study. Over 400,000 patients undergo CABG surgery each year in the USA and some loss of brain function has been reported in up to 70% of patients."

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The Phase 3 trial is aimed at assessing Glypromate's® effectiveness as a protection from neurocognitive disturbance following CABG. Impaired cognition is a known complication of CABG. 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.

The FDA's decision is subject to the provision of additional data on stability, toxicology and pharmacokinetics of the compound, normal requirements for Phase 3 trials. The standard requirement for drug approval to market are two major efficacy studies, and the planned study would constitute one of these.

### **About Glypromate®**

Glypromate® is a naturally-occurring peptide fragment which is found in normal brain tissue. When injected intravenously, Glypromate® has been shown to act by multiple pathways in protecting brain tissue from injury. Glypromate® is a potential therapeutic candidate for any disease 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 72 patents across five product families, targeting markets with large unmet needs and limited competition. Neuren has two lead candidates, Glypromate® and NNZ-2566, targeting a range of acute neurological conditions. Neuren has commercial and development partnerships including Pfizer and the US Army's Walter Reed Institute of Research.

For more information, please visit the company's website at [www.neurenpharma.com](http://www.neurenpharma.com)

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