US FDA approves Neuren's Phase 3 IND for Glypromate® Trial

Key points

- Neuren to initiate Phase 3 trial following the US FDA's approval of the IND
- Currently no treatments available to prevent cognitive impairment caused by cardiac bypass
- Phase 3 trial conducted under US FDA authorisation moves Glypromate® towards a first in market position for a US$1 billion market

Wednesday 31 January 2007: Neuren Pharmaceuticals Ltd (ASX: NEU) today announced that the US Food and Drug Administration (FDA) has accepted its investigational new drug application (IND) and authorised the Company to proceed with its Phase 3 trial to prevent cognitive impairment following major cardiac surgery using Glypromate®.

Neuren has engaged a US-based, international contract research organisation to manage the global trial of 520 patients which will be carried out in the US, Australia and New Zealand. This Phase 3 trial is double blind, multi-centred, placebo controlled and is based on endpoints that have been well-established in previous FDA-approved studies using validated measurement techniques. The trial is estimated to take 18 months.

The Phase 3 trial is budgeted to cost Neuren A$10 million, which is substantially less than many other Phase 3 trials.

There are currently no treatments available to prevent cognitive impairment following cardiac surgery, which is experienced by up to 70% of patients at discharge and more than one-third of patients at three months following surgery. Loss of cognitive function has been shown to negatively impact quality of life for cardiac surgery patients and is recognised as an important therapeutic target by the American Heart Association and the American College of Cardiology, and has previously been accepted as a condition requiring treatment by the US FDA.

In 2005, the FDA recommended that Neuren advance Glypromate® into a Phase 3 study. Neuren has now successfully completed additional testing of the drug in both volunteers and cardiac surgery patients. The Company believes that authorisation from the FDA to proceed with the planned Phase 3 trial confirms that Neuren's clinical development program meets international standards and positions Glypromate® to be first in a market estimated at US$1 billion.

Neuren also believes that the combination of the drug's unique attributes and the advantages of targeting cognitive impairment in cardiac surgery patients gives Glypromate® a significantly improved chance of a successful outcome, particularly in comparison to neuroprotective therapies targeted toward stroke. In multiple studies in animals, Neuren has demonstrated that Glypromate® can significantly reduce brain damage when it is administered up to 7-11 hours after the initial injury, an important

advantage in preventing brain damage caused by the type of injury resulting from cardiac surgery. Glypromate® also protects multiple types of brain cells via a unique set of biological actions, protecting the physical structure around the brain's neurons as well as the neurons themselves. In addition to providing significant protection of the brain, the compound has an excellent safety profile which will be critical for drug approval.

Neuren is continuing technical discussions with the FDA on remaining methodological details of the study in order to ensure that results from the study will support registration for Glypromate® in the US. Prior to enrolling the first patient, the Company may make modifications to the protocol based on these discussions.

Mr David Clarke, Chief Executive Officer of Neuren said: "We are delighted that our strategy for developing Neuren's lead drug to US FDA standards has been reinforced by this FDA response. This represents a major milestone in the development of both Glypromate® and Neuren."

"We were the first company in Australasia to file our IND electronically, which was a major undertaking, but will make future discussions around potential partnering and eventual submission of the application for regulatory approval much more efficient," Mr Clarke added.

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 US 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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