Neuren reports successful NNZ-2566 safety trial results

Key points

- Neuren successfully completes a Phase 1 study for NNZ-2566
- Safety of NNZ-2566 at high dose infusion confirmed
- NNZ-2566 development on track for Phase 2 trials in 2007

Wednesday, 17 January 2007: Neuren Pharmaceuticals Ltd (ASX: NEU) has successfully completed a Phase 1 safety and tolerability trial of its second lead candidate, NNZ-2566, which is being developed to treat traumatic brain injury (TBI).

The results from the study were referred to the independent Data Safety Monitoring Committee for review who confirmed the safety profile of the drug.

The Phase 1 trial involved 28 healthy volunteers in four groups who received one of four escalating doses of NNZ-2566 (0.1,1.0,10.0,20.0 mg/kg) and was conducted at the Centre for Clinical Studies, Alfred Hospital in Melbourne.

The maximum dose was 20 mg/kg, delivered over a 10-minute period of infusion. This dose significantly exceeded that of Neuren's lead compound, Glypromate®, for which the maximum Phase 1 dose was 3 mg/kg/hr in a 15-minute and 4-hour infusion. An extension of the NNZ-2566 Phase 1 trial is anticipated to run early in 2007 to evaluate pharmacokinetics with longer infusions of 12 or 24 hours, which takes into account the often greater severity of TBI.

Neuren's NNZ-2566 has been developed in collaboration with the US Army's Walter Reed Army Institute of Research. Planning is now well under way for a Phase 2 trial in patients with TBI, to take place in 2007. The target market for TBI is estimated at US$1.5 billion in the US alone.

Mr David Clarke, Chief Executive Officer of Neuren, said: "It is great to have confirmation that NNZ-2566 is safe. The dosing regime should provide us with greater flexibility for the Phase 2 trial, due to start this year. We are also exploring other opportunities for NNZ-2566 such as vascular dementia and stroke-related injuries."

About NNZ-2566

NNZ-2566 is a novel molecule that has a profile suitable for both intravenous infusion and chronic oral delivery. It has been shown to be protective in numerous in vitro and in vivo models of brain injury, and is currently in development to treat traumatic brain injury. Since 2004, NNZ-2566 has been developed in collaboration with the US Army's Walter Reed Army Institute of Research under a Cooperative Research and Development Agreement which includes Clinical Protocol development and regulatory filings.

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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