Neuren completes pre-clinical FDA requirements to progress Glypromate® to Phase 3

1 February 2006: Neuren Pharmaceuticals Ltd (ASX: NEU) announced today the successful completion of the additional pre-clinical requirements outlined by the US Food and Drug Administration (FDA). This enables the Company, along with the completion of the ongoing Phase 2a trial report, currently on plan for March/April, to move straight into a Phase 3 major efficacy trial for its lead molecule, Glypromate®. The Phase 3 trial will be conducted under a US IND (Investigational New Drug) application and is planned to commence in the last quarter of 2006.

Following a meeting with the FDA in April 2005, it was agreed that Neuren would conduct additional work that would enable the Company to move Glypromate® directly into a pivotal FDA Phase 3 trial, avoiding a Phase 2b trial and saving Neuren approximately $6-8 million and 2 years in the development programme. The additional preparatory pre-clinical package was a major part of the FDA requirements.

The additional FDA pre-clinical requirements for a Phase 3 trial were to:

(i) Conduct additional toxicology studies;
(ii) Conduct further assay validation of the bioanalytical method for Glypromate® in plasma and/or blood for all species used;
(iii) Conduct animal studies to confirm the distribution of Glypromate® in normal, healthy brain tissue;
(iv) Conduct an *in vivo* test for chromosomal damage using rodent hematopoietic cells;
(v) Initiate manufacturing and accompanying stability studies in accordance with FDA guidelines relevant to pivotal Phase 3 clinical trials.

These items have been successfully addressed, in the following manner:

(i) Additional toxicology studies have been completed, with full assessment of clinical signs, body weight, organ weights, blood chemistry assessment, urinalysis and microscopic histopathological analysis. No drug-related toxicology was observed in either study at doses more than 50 times higher than those employed in the Phase 2a study;
(ii) All bioanalytical methods have been developed and fully validated externally;
(iii) Independent *in vivo* microdialysis studies have clearly demonstrated the presence of Glypromate® in healthy animal brains after intravenous infusion;
(iv) A micronucleus assay has been conducted to demonstrate that Glypromate® does not induce chromosomal damage in this assay;
(v) Manufacturing and stability studies of trial supplies are to Phase 3 Good Manufacturing Practice (GMP)

These studies further demonstrate the safe, non-toxic and stable profile of Glypromate® and build on previous pre-clinical data. Dr Mike Bickerdike, Head of Pre-clinical Development said: “The completion of these studies is an important milestone in the clinical development of Glypromate®. Not only have we met the additional pre-clinical requirements placed on us for a Phase 3 study under a US IND, we can draw further comfort from the extremely safe pre-clinical profile we see with the compound.”

.

About Glypromate®
Glypromate® is derived from a naturally occurring peptide that 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 diseases caused through chronic or acute brain injury.

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® 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

Contact details

Company	Media and investor relations
David Clarke CEO Neuren T: 1800 259 181 (Australia) T: +64 9 3 367 7167 ext 82308(New Zealand) M: +64 21 988 052	Rebecca Piercy Buchan Consulting T: +61 3 9866 4722 M: +61 422 916 422