# Neuren receives “may proceed” letter from US FDA for oral NNZ-2566 clinical trials

**SYDNEY, Australia, 22 December 2011**: The US Food and Drug Administration (FDA) has authorised Neuren to initiate human clinical trials under an Investigational New Drug (IND) application for the oral formulation of NNZ-2566. Selection of an aqueous oral formulation of NNZ-2566 enabled Neuren to complete the pre-clinical requirements for IND filing ahead of schedule and at lower cost than was originally anticipated. This approval will enable the Company to proceed with a planned Phase I trial in healthy volunteers in preparation for Phase II clinical trials in patients with concussion and Rett Syndrome. The Phase I study is expected to start in January 2012 with the other studies beginning Q2/Q3 2012 depending on reviews of protocols by the FDA and Institutional Review Boards (the US equivalent of Ethics Committees) at participating clinical sites.

Commenting on the FDA action, Larry Glass, Neuren’s CEO, said: “This is an important step for the Company. A stable, easy to administer oral formulation of a potent neuroprotective molecule potentially opens the door for the treatment of chronic neurological conditions such as Rett Syndrome and the treatment of patients with milder injuries outside of emergency departments or trauma centers. These are larger markets than acute treatment of moderate to severe head injury and also represent conditions with critical unmet clinical need for which no effective therapies are available.”

**About NNZ-2566**

NNZ-2566 is a patented, synthetic analogue of the n-terminal tripeptide of IGF-1, a naturally occurring molecule with potent neuroprotective effects in animal models of stroke and head injury. The principal mechanism by which NNZ-2566 exerts its neuroprotective effects is by inhibiting the expression of inflammatory molecules (cytokines) following brain injury. NNZ-2566 also significantly reduces activation of microglia, a type of brain cell involved in the immune response in the central nervous system, but which can result in excessive inflammation following brain injury resulting in additional damage. NNZ-2566 also has been shown to dramatically reduce the incidence of convulsive and non-convulsive seizures in multiple brain injury models. Studies have shown that NNZ-2566 is effective when administered both as an intravenous infusion and in oral form. NNZ-2566 has been in development as a treatment for TBI under a collaborative research and development agreement between Neuren and the US Army since 2004. The US Army has committed approximately US$23 million to support the NNZ-2566 program.

**About Neuren**

Neuren Pharmaceuticals is a biopharmaceutical company developing new therapies for brain injury, chronic neurological diseases and cancer. Neuren presently has two clinical-stage molecules, NNZ-2566 and Motiva®, in Phase II clinical trials largely funded by the US Army and the National Health and Medical Research Council, respectively. Through its subsidiary, Perseis Therapeutics Limited, Neuren is developing monoclonal antibodies against Trefoil Factors 1 and 3, proteins produced by cancer cells that are associated with cancer spread and reduced patient survival.

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