Neuren completes first patient cohort in NNZ-2566 Phase II clinical trial

DSMC authorises progression to cohort 2

SYDNEY, Australia, 9 May 2011: Neuren Pharmaceuticals (ASX:NEU) announced today that enrolment of the first cohort of 30 patients in the Phase II *INTREPID*$^{-2566}$ trial has been completed and that data on safety have been reviewed by the independent Data and Safety Monitoring Committee (DSMC). Following the review, the DSMC has recommended progression to the second cohort. Enrolment of cohort 2 will begin immediately.

Commenting on this milestone, Larry Glass, Neuren's CEO, said: "We're pleased that cohort 1 has been completed and that the DSMC has authorized moving to the next cohort. The committee's decision supports our belief that NNZ-2566 appears to be safe and well-tolerated even in severely compromised patients. The pace of enrolment has picked up and should continue to accelerate with inclusion of female patients, an expanded age range, 8 additional sites and eventually exception from informed consent."

About the Phase II dose-escalation cohorts

The Phase II clinical trial is evaluating the safety and efficacy of intravenous administration of NNZ-2566 in patients with moderate to severe traumatic brain injury. The drug is administered within 8 hours of injury via a 10 minute bolus followed by 72 hours of continuous infusion. There are 3 cohorts in the study. All patients receive the same bolus (20 mg/kg/hr). The first 30 patients (cohort 1) received a low-dose infusion (1 mg/kg/hr). The next 30 patients (cohort 2) will receive a medium-dose infusion (3 mg/kg/hr). The third cohort will comprise 200 patients all of whom will receive the highest infusion dose (6 mg/kg/hr). All doses are expected to provide blood levels of the drug in patients that are comparable to the range in which efficacy was confirmed in animal models of brain injury.

About NNZ-2566

NNZ-2566 is a patented, synthetic analog of the n-terminal tripeptide of IGF-1, a molecule with potent neuroprotective effects in stroke and head injury models. The principal mechanism by which NNZ-2566 is believed to exert neuroprotective effects is by limiting 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$22 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 2 clinical trials largely funded by the U.S. 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. For more information, please visit www.neurenpharma.com.

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