



Study of Second Neuren Drug to be Initiated; Clinical Trial of Motiva™ Funded by Australian Government Grant

SYDNEY, Australia, 3 March 2010: Neuren Pharmaceuticals (ASX:NEU) announced today that a Phase II clinical trial of Motiva™ in patients with post-stroke apathy has been funded by a project grant from the National Health and Medical Research Council to the University of Western Australia. Funds approved for the grant will cover virtually all costs associated with the study other than the drug itself which will be provided by Neuren from existing stock. The principal investigator for the study is Professor Sergio Starkstein, MD, PhD, Winthrop Professor and Head of the Neuropsychiatry Unit at Fremantle Hospital, an international expert on apathy and depression in patients with stroke and other neurological diseases. Patient enrollment is expected to begin this month.

Neuren's right to develop Motiva™ (chemical name: nefiracetam) was obtained via the acquisition of Hamilton Pharmaceuticals in 2007. A previous Phase II study of Motiva™ in post-stroke patients with depression showed a statistically significant benefit for patients with apathy. Apathy is a potentially debilitating syndrome that occurs frequently among patients who have had a stroke as well as patients with depression, Parkinson's disease, traumatic brain injury, schizophrenia and many other neurological and psychiatric conditions. Apathy often has deleterious effects on patients' functional capacity and ability to perform normal activities of daily living. There presently are no drugs approved for this indication and none — including antidepressant medications — that have been shown to be effective in treating apathy.

Commenting on the pending trial, Professor Starkstein said: "Post-stroke apathy is a major concern for patients, families and health care providers. Apathy after stroke is associated with longer hospital stays, impaired rehabilitation and worse functional outcomes. Post-stroke patients with apathy engage poorly in rehabilitation programs which hampers their physical and social recovery. Results from the previously completed trial in this population are encouraging and we are hopeful that the drug's benefits will be confirmed in this new study."

If the results of the new trial are positive, Neuren plans to pursue pivotal (registration) trials under the open US IND it already has in place. The Company also is evaluating opportunities to conduct trials of Motiva™ to treat apathy in other conditions such as Parkinson's disease in which apathy is prevalent.

About the upcoming trial

The NHMRC project grant of A\$824,000 was awarded to Winthrop Professor Sergio Starkstein, Professor David Bruce, Winthrop Professor Osvaldo Almeida, Professor Robert Robinson and Assistant Professor Wendy Davis for "A Randomised Double Blind Placebo Controlled Study of Nefiracetam in Patients with Post-Stroke Apathy". The trial will be conducted at the Fremantle and Royal Perth Hospitals and will seek to enroll 122 patients randomized 1:1 between drug and



pharmaceuticals

placebo. Patients will receive 900 mg/day of Motiva™ or placebo for 12 weeks. The effect of the drug on apathy and functional capacity will be assessed after 12 and 36 weeks.

About the previously completed clinical trial

Approximately 51% (70/137) of patients with post-stroke depression met published criteria for apathy. Patients were randomly assigned to 600 mg/day or 900 mg/day of Motiva™ or placebo. Among patients treated for at least 4 weeks, those who received the 900 mg/day dose showed a significantly greater change in Apathy Scale scores than those receiving 600 mg/day of Motiva™ or placebo. [Robinson RG, Jorge RE, Clarence-Smith K and Starkstein S. Double blind treatment of apathy in patients with post-stroke depression using nefiracetam. *Journal of Neuropsychiatry and Clinical Neurosciences* 21:2, Spring 2009]

About Neuren

Neuren Pharmaceuticals is a biopharmaceutical company developing novel therapeutics in the fields of brain injury, neurological diseases and conditions, and cancer. The Neuren portfolio comprises seven product families targeting markets with large unmet needs and limited competition. Neuren has two clinical-stage molecules — Motiva™ and NNZ-2566 — focused on a range of acute and chronic neurological conditions as well as a number of drug discovery programs focused on important targets in neurology and, through its subsidiary Perseis Therapeutics Limited, oncology. For more information, please visit www.neurenpharma.com.

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