

US Army presents new Neuren research results at international neuroscience meeting

Key Points:

- **US Army reports further positive results in experiments with NNZ-2566 in stroke**
- **Results confirm benefits of NNZ-2566 in reducing non-convulsive seizures**
- **Study further supports use of brain wave measurement as a sensitive, cost-effective tool for use in human clinical trials**

Monday 29 May 2006: The US Army's Walter Reed Army Institute of Research (Walter Reed) recently presented positive results in a stroke model for Neuren's second lead compound NNZ-2566 at the 8th International Neurotrauma Symposium in Rotterdam, The Netherlands. Walter Reed's paper, "NNZ-2566 Treatment Reduces Non-Convulsive Seizures in a Rat Model of Middle Cerebral Arterial Occlusion (MCAO)" presented data and analyses confirming that NNZ-2566 inhibits non-convulsive seizures (NCS).

In line with previous Walter Reed research on Neuren's NNZ-2566 for Traumatic Brain Injury (TBI), Walter Reed have again presented and supported NNZ-2566's results this time in a new area of development i.e. models of stroke, demonstrating its wide applicability to various types of brain injury and reinforcing the continued support of the Walter Reed team and NNZ-2566's important role in their drug development programme.

Neuren's internal research also has found a considerable benefit in stroke and ischemic brain injury models and showed significant reduction in injury size (infarct volume) for both the intravenous (iv) and oral forms of NNZ-2566.

The final conclusion of the Walter Reed paper is that: "NNZ-2566 appears to be an excellent drug for the treatment of the NCS induced by severe ischemic brain injury".

NCS can occur as a result of severe brain injury and are a feature of brain wave abnormalities that have been found to be an important predictor of patient recovery, as well as being a target for therapeutic intervention.

The results reported by Walter Reed demonstrate that NNZ-2566 reduced the proportion of animals exhibiting seizures as well as significantly reducing the number of NCS per animal and the total time in seizure in a dose-dependent manner. This confirms and expands upon previously reported positive results obtained by Walter Reed in models of traumatic brain injury (TBI) from studies conducted with Neuren's NNZ-2566.

In the control animals that did not receive NNZ-2566, the majority of NCS occurred within the first 4 hours following injury, with an additional, delayed phase of NCS activity at 7-8 hours post injury. This latter phase was completely inhibited by NNZ-2566 treatment.

Neuren and Walter Reed have filed a joint patent covering the use of NNZ-2566 to prevent NCS. NNZ-2566 has recently entered Phase 1 clinical trials in Australia. The Phase 1 trial dosing of the first cohort has been completed and the Phase 1 trial is on track. Another Neuren compound, Glypromate[®], is poised to enter a Phase 3 trial this year, having recently successfully completed a Phase 2a study.

Mr David Clarke, CEO of Neuren Pharmaceuticals, said: “The results reported by the Walter Reed continue to reinforce NNZ-2566 as a therapy for acute brain injury, both in stroke and TBI.”

Dr Doug Wilson, Chief Medical Officer, also noted “The experimental effects of the drug on electroencephalographic abnormalities, combined with other studies by Neuren and the Walter Reed assessing the effects of NNZ-2566 on functional recovery and the size of brain injuries, are encouraging.”

Neuren is currently designing Phase 2 clinical trials of NNZ-2566 and plans to incorporate measurements of brain wave changes as one of a number of innovative approaches to examine the benefits of NNZ-2566 in stroke and other indications.

There are currently no effective treatments for stroke on the market. A drug that is effective for acute treatment of ischemic and haemorrhagic stroke would potentially be applicable to 800,000 patients in the US alone and has an estimated market size of US\$3.5 billion worldwide.

Appendix:

The study was conducted in a rat model of brain injury-induced seizures using the validated and widely-used permanent middle cerebral artery occlusion (MCAO) model. EEG activity was recorded continuously for 24 hours and analysed for incidence of seizures and number of non-convulsive seizures (NCS) per rat.

The study involved 13 control animals that received vehicle only and a total of 34 animals that received one of three doses of NNZ-2566. The dosing regimen for animals receiving drug was a 3, 10 or 100 mg/kg bolus administered 30 minutes after injury followed immediately by a 12-hour infusion (iv) at 3 mg/kg/hr. Results are presented in the following table.

| | Vehicle (n=13) | 3mg/kg (n=11) | 10mg/kg (n=12) | 100mg/kg (n=11) |
|------------------|-------------------|------------------|----------------|--------------------|
| % Rats with NCS | 92% (12/13) | 64% (7/11) | 76% (9/12) | 36% (4/11)* |
| NCS/rat | 19.2 ± 6.0 | 13.3 ± 4.6 | 6.2 ± 1.8* | 5.1 ± 2.6* |
| Total Time (sec) | 1300 ± 368.8 | 577 ± 209.3 | 323 ± 118.0 * | 252 ± 134.9* |

(*p<0.05 compared to vehicle)

About NNZ-2566

NNZ-2566 is a neuroprotectant related to Glypromate[®], a compound that occurs naturally in the brain. Glypromate[®] is Neuren's most advanced drug candidate.

Glypromate[®] has successfully completed Phase 2a clinical trials in Australia and New Zealand and is expected to enter Phase 3 clinical trials in late 2006. In late 2004, Neuren entered into a Material Transfer Agreement with Walter Reed under which the Institute performed preliminary testing of NNZ-2566 in an animal model of traumatic brain injury. Following positive results from those preliminary studies, Neuren and the Army executed a follow-on Cooperative Research and Development Agreement (CRADA) to further develop NNZ-2566 as a therapy for traumatic brain injury. Under the agreement, the Institute is conducting additional tests of NNZ-2566 and optimising the dose and timing of administration in animal models while Neuren is responsible for manufacturing, pharmacology and toxicology.

About Walter Reed Army Institute of Research

Walter Reed is the largest, most diverse, and oldest laboratory in the US Army Medical Research and Materiel Command. It conducts research on a range of military relevant issues, including naturally occurring infectious diseases, combat casualty care, operational health hazards, and medical defence against biological and chemical weapons. Walter Reed is the Department of Defense's lead agency for infectious disease research and a crucial source of research support for medical product development.

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

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