



US Walter Reed Army contract for NNZ-2566 expanded

Key points:

- **New results confirm previous 50% effectiveness and now 70% result**
- **This re-confirms the potential for human clinical trials**
- **Neuren to be included in expanded US Army TBI development program incorporating a model of a potentially new clinical end point**
- **Walter Reed funding half of the preclinical research costs**
- **NNZ-2566 clinical trial program on budget**
- **Neuren retains all future commercial rights outside the US military**

Monday 11 July 2005: Neuren Pharmaceuticals Ltd (ASX: NEU) announced today that its agreement with the Walter Reed Army Institute of Research ("Walter Reed") to develop the Company's second lead compound, NNZ-2566, as a therapy for traumatic brain injury ("TBI") has been expanded. Walter Reed is the leading medical research institute of the US Army and is based in Washington DC.

Preclinical results from the NNZ-2566 studies show that the benefit of administration following injury has increased from the already significant 50% reduction in neurological deficit to a 70% reduction with longer drug exposure.

Walter Reed has developed a specialised model to predict clinical outcome in TBI by utilising an easy to detect early clinical event that may potentially be a quicker and more cost effective method than currently used in clinical trials. Neuren has been selected to work with Walter Reed to explore the value of this model as a simpler model for testing TBI therapies in human clinical trials.

Under the current agreement, Walter Reed funds half of the preclinical research relating to NNZ-2566, with Neuren retaining all future commercial rights outside the US military.

"It is great to have the support of such a recognised and respected institute as Walter Reed. The research team judged previous results showing a 50% reduction in impaired behavioural outcome as impressive and sufficient evidence of efficacy to justify progression into a human clinical trials programme. The latest data confirms this and now shows 70% effectiveness using a longer drug exposure," said Mr David Clarke, CEO of Neuren.

"This, along with the previous finding that NNZ-2566 down-regulates microglia which leads to a reduction in the critical inflammatory effect in these types of injuries, increases our confidence in moving this project into human clinical trials. This all helps in



increasing the strength of our NNZ-2566 portfolio. We are now entering into discussions with the US Army for the third stage i.e. moving into clinical trials,” added Mr Clarke.

About NNZ-2566

NNZ-2566 is a neuroprotectant related to Glypromate[®] which is Neuren’s most advanced drug candidate. Glypromate[®] has successfully completed Phase I clinical trials in Australia and is expected to enter Phase II clinical trials in late 2005. 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 Walter Reed 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. If the results of the preclinical research warrant testing in humans, Neuren and Walter Reed will cooperate in preparing an Investigational New Drug (“IND”) application to evaluate the drug in human patients and the CRADA will be modified to include clinical trials of NNZ-2566.

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 neuroprotection and metabolic disorders. The Neuren portfolio consists of five 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 neurological conditions. Neuren has commercial and development partnerships, including with Pfizer, the US Army’s Walter Reed Army Institute of Research and Metabolic Pharmaceuticals.

For more information, please visit the Company’s website at www.neurenpharma.com

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Appendix

The preclinical efficacy studies performed by Walter Reed utilise a proprietary experimental model of traumatic brain injury.

In standardising and validating the model, Walter Reed scientists with whom Neuren collaborates have found that the most sensitive and reliable measure of drug effect is functional recovery at 72 hours determined by the ability of the animals to traverse a balance beam expressed as percent reduction in deficit compared to controls.

The number of times that the animal steps off the beam (foot faults) on one side is an indication of neurological damage on the opposite side.

In the first and second series of experiments performed with NNZ-2566, the drug was administered 30 minutes after the injury was induced. Neurological deficit was assessed 24 and 72 hours following injury.

In addition, as Neuren believes that one of NNZ-2566's modes of action involves inhibition of microglia activation, Walter Reed also evaluated this outcome using immunohistochemical staining which was found to be reduced by a statistically significant 47%.

The following table summarises the results of the 72-hour observations of neurological deficit.

DOSE	INFUSION TIME	TREATED ANIMALS	CONTROL ANIMALS	PERCENT REDUCTION	P VALUE
0.3 mg/kg/hr	4 hours	9	10	-5.3%	n/a
3.0 mg/kg/hr	4 hours	9	10	53.8%	n/a
1.0 mg/kg/hr	12 hours	11	11	58.0%	0.03
3.0 mg/kg/hr	12 hours	9	11	69.9%	0.01