



US Department of Defense Approves Funding for NNZ-2566 Trials

Key Points:

- **Neuren-US Army proposal for two NNZ-2566 Phase II trials approved**
- **US Department of Defense to cover US\$4m of Phase II costs**
- **Trials to be undertaken as a collaborative project with US Army**
- **US Army scientist to serve as Principal Investigator**

Monday, 21 January 2008: Neuren Pharmaceuticals (ASX:NEU) today announced that the US Department of Defense (DOD) has approved a proposal by the US Army Walter Reed Army Institute of Research (WRAIR) to provide US\$4 million in funding for the Company's second lead compound NNZ-2566. NNZ-2566 is due to begin Phase II clinical trials for traumatic brain injury (TBI) in association with WRAIR.

The proposal was submitted to the DOD's Congressionally Directed Medical Research Program in response to a solicitation for grants in TBI and Post-traumatic Stress Disorder. It represented a joint effort by Neuren, WRAIR and the Geneva Foundation, a non-profit organisation created to foster research to advance military medicine. Under this arrangement, Neuren will ultimately be responsible for regulatory interactions with the US Food and Drug Administration (FDA) and for design and implementation of the trials. WRAIR will support Neuren's interaction with the FDA and, through Geneva, will provide some of the clinical trials personnel as well as direct reimbursement of participating clinical sites and related expenses.

Dr. Frank Tortella, Chief of the Department of Applied Neurobiology at WRAIR and an internationally-recognised expert in TBI, will serve as the Principal Investigator for the grant. Since 2005, when Neuren first entered into a Collaborative Research and Development Agreement with WRAIR, Dr. Tortella has led the Army's collaboration with Neuren to study the efficacy and mechanisms of action of NNZ-2566 in TBI. His team has been responsible for identifying the effects of Neuren's drug on non-convulsive seizures as well as on genes responsible for inflammatory and apoptotic (programmed cell death) responses to brain injury.

Sites and principal investigators that have agreed to participate in the trials include:

- M. Ross Bullock, MD, PhD, Professor of Neurological Surgery, University of Miami Miller School of Medicine
- Paul Vespa, MD, Associate Professor of Neurology and Neurosurgery and Director of Neurocritical Care, University of California Los Angeles
- James Ecklund, MD, Chairman of Neurosciences at INOVA Fairfax (Virginia) Hospital (former Chief of Neurosurgery, Walter Reed Army Medical Center)
- Jeffrey Bazarian, MD, MPH, Associate Professor, Departments of Neurology and Emergency Medicine, University of Rochester (New York)
- COL John Holcomb, MD, Commander, US Army Institute of Surgical Research, Brooke Army Medical Center (Texas)
- Dr Tim Anderson, Neurologist, Christchurch Hospital (NZ)
- Mr Ed Mee, Neurosurgeon, Auckland Hospital (NZ)

- Dr Bhavani Peddinti, Head of Emergency Department, Middlemore Hospital (Auckland, NZ)

Larry Glass, Neuren's Co-CEO said: "This is a significant outcome for the Company, reflecting recognition of the results of more than three years of joint research and development by Neuren and the US Army. This has been an extraordinary collaboration and has brought NNZ-2566 to the point where we will finally be able to determine whether the drug can make a difference for patients where the need is so great and the options so few."

Two clinical trials with NNZ-2566 will be initiated in 2008 —one in severe TBI and one in mild to moderate TBI. The Phase II trials are due to start in mid 2008 and will be conducted in the United States and New Zealand in collaboration with the US Army. Results are expected to be released in late 2009.

About NNZ-2566

NNZ-2566 is a synthetic analogue of Glypromate[®], Neuren's lead drug, currently undergoing a Phase III trial to reduce cognitive impairment in patients undergoing cardiac surgery with cardiopulmonary bypass. Glypromate[®] is a naturally-occurring neuropeptide derived from Insulin-like Growth Factor 1 (IGF-1). The neuroprotective properties of NNZ-2566 are believed to derive from inhibition of inflammatory and apoptotic (cell death) processes that can result from TBI, possibly by preventing activation of microglia, part of the cellular inflammatory response to brain injury. NNZ-2566 also attenuates non-convulsive seizures that occur following brain injury. A Phase Ib safety study of NNZ-2566 was completed in late 2007 and the drug was found to be safe and well-tolerated in normal, healthy volunteers. NNZ-2566 has been the subject of a Collaborative Research and Development Agreement with the US Army Walter Reed Army Institute of Research since 2005 to evaluate the drug as a candidate therapeutic for TBI.

About Neuren Pharmaceuticals

Neuren Pharmaceuticals (ASX: NEU) is a biopharmaceutical company developing novel therapeutics in the fields of brain injury and diseases and metabolic disorders. The Neuren portfolio consists of eight product families, targeting markets with large unmet needs and limited competition. Neuren has four lead candidates, Glypromate[®], Motiva[™], NNZ-2566 and NNZ-2591 targeting a range of acute and chronic neurological conditions.

For more information, please visit Neuren's website at www.neurenpharma.com.

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