

## Neuren announces increase of US\$3 million to US Army grant and updates INTREPID clinical trial enrolment outlook

**Melbourne, Australia, 17 July 2014:** Neuren Pharmaceuticals (ASX: NEU) announced today that the grant award supporting its collaboration with the US Army on the development of potential therapies for traumatic brain injury (TBI) has been increased by approximately US\$3 million and extended to 31 December 2015. Neuren expects to receive the additional grant amount over the next 12 months.

The grant provides funding towards Neuren's third party costs associated with the Phase 2 clinical trial of NNZ-2566 in moderate to severe TBI (the "INTREPID" trial) and the Phase 2 clinical trial of NNZ-2566 in mild TBI (concussion).

The approval of the extension and increase to the grant award was critical to enable Neuren to proceed fully with its strategy to accelerate enrolment of subjects into the INTREPID trial. Up to 10 additional trauma centres in the United States will begin enrolment of subjects during the second half of 2014, after approval for each centre is received from the Human Research Protection Office (HRPO) of the US Army Medical Research and Materiel Command. The rate of enrolment at the existing 12 trauma centres in the United States has already increased significantly in recent months, following the completion of enrolment in competing clinical trials. Since 1 June 2014, 13 subjects have been enrolled into the INTREPID trial, raising the total to 162 subjects at 16 July 2014.

The extension and increase to the grant award has resolved uncertainty concerning the trial funding and timelines, however the later activation of the additional trauma centres means that Neuren now expects to be able to complete enrolment of 260 subjects in the first half of 2015 (was by the end of 2014) and announce top-line results from the trial in the second half of 2015 (was first half of 2015).

The blinded data from the trial to date demonstrate that NNZ-2566 appears to be safe and well-tolerated and that the mortality rate to date is lower than expected. Three biomarkers of brain injury are being collected during the first 72 hours following injury, beginning prior to administration of the study drug or placebo. Neuren believes that these biomarkers will serve as a central component when it completes the INTREPID trial and analyses the un-blinded trial data for signs of clinical efficacy. In April 2014, Neuren presented data at the 4<sup>th</sup> Annual Traumatic Brain Injury Conference in Washington DC, indicating that the biomarkers are highly sensitive, specific and statistically significant predictors of clinical outcome. These findings are expected to help control for underlying heterogeneity in the subject population, which historically in TBI trials has been a challenge when assessing clinical efficacy.

Neuren Executive Chairman Richard Treagus commented; "We are pleased that the US Army has increased the level of support for our ongoing collaboration, as we aim to demonstrate the potential for NNZ-2566 to help mitigate the serious health and economic ramifications of both severe and mild traumatic brain injury in military and civilian communities. Neuren is committed to completing and reporting results from both clinical trials in 2015".

### **About traumatic brain injury and Neuren's NNZ-2566**

Each year, approximately 1.7 million people sustain a traumatic brain injury (TBI) in the US alone. Of these, 25% are classified as moderate to severe while the remaining 75% are classified as mild TBI or concussion. TBI is a contributing factor in one-third of all injury-related deaths. Moderate to severe TBI frequently leave patients with profound physical, emotional and cognitive disabilities, often requiring life-long institutional or other supportive care. Concussion also can result in long-term or permanent impairments and disabilities. The direct medical costs and indirect costs of TBI are estimated to exceed US\$48 billion per year in the US. The potential global market for TBI and concussion is estimated at more than \$4 billion.

NNZ-2566 is a synthetic analogue of a naturally occurring neurotrophic peptide derived from IGF-1, a growth factor produced by brain cells. In animal models, NNZ-2566 has been shown to inhibit neuroinflammation, normalize microglial function, restore synaptic signalling and increase IGF-1 expression in the brain. Improvements in cognitive function, affected behaviours and synaptic signalling have also been observed in association with these cellular and molecular effects.

### **About Neuren**

Neuren Pharmaceuticals Limited (Neuren) is a publicly listed biopharmaceutical company focusing on the development of new therapies for brain injury, neurodevelopmental and neurodegenerative disorders. The novel drugs target chronic conditions such as Rett Syndrome and Fragile X Syndrome as well as acute neurological injuries. Neuren presently has a clinical stage molecule, NNZ-2566 in four Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development. The intravenous form of NNZ-2566 is presently in a Phase 2 clinical trial in patients with moderate to severe traumatic brain injury. The oral form of NNZ-2566 is in Phase 2 trials in Rett Syndrome, Fragile X Syndrome and Concussion. Three programs have received Fast Track designation from the US FDA and the Fragile X Syndrome program has also received Orphan Drug designation.

### *Forward-looking Statements*

*This ASX-announcement contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this announcement.*

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