Neuren Announces Trofinetide as Proposed International Nonproprietary Name for NNZ-2566

Melbourne, Australia, 28 January 2015: Neuren Pharmaceuticals (ASX: NEU) today announced that in the World Health Organization’s latest publication of proposed International Nonproprietary Names for Pharmaceutical Substances (INN), trofinetide has been included as the proposed INN for glycyl-2-methyl-L-prolyl-L-glutamic acid, which is currently designated by Neuren as NNZ-2566. The proposal is subject to a four-month period for comment before trofinetide can be confirmed as the INN.

Neuren is developing NNZ-2566 as a novel therapy for a range of neurological conditions and injuries. In November 2014, Neuren announced top-line results from its Phase 2 clinical trial in Rett syndrome, which successfully demonstrated clinical benefit from treatment with NNZ-2566. Three other Phase 2 trials are in progress for Fragile X syndrome, moderate to severe traumatic brain injury and concussion.

“Subject to completion of the World Health Organization’s selection procedure, we look forward to replacing the name NNZ-2566 with trofinetide as we continue to progress through the development and commercialisation process”, commented Neuren Executive Chairman, Richard Treagus.

About NNZ-2566 (Proposed INN: trofinetide)

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 exhibits a wide range of important effects including inhibiting neuroinflammation, normalizing the role of microglia and correcting deficits in synaptic function. NNZ-2566 is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. 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 development in Rett syndrome, Fragile X syndrome and mild traumatic brain injury (concussion). Three programs have received Fast Track designation from the US FDA and the Fragile X syndrome program has also received Orphan Drug designation.

About Neuren

Neuren Pharmaceuticals Limited (Neuren) is a biopharmaceutical company developing new therapies for brain injury, neurodevelopmental and neurodegenerative disorders. The novel drugs target chronic conditions as well as acute neurological injuries. Neuren presently has a clinical stage molecule, NNZ-2566 in Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development.
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.

For more information, please contact:
Dr Richard Treagus, Executive Chairman: rtreagus@neurenpharma.com ; +61 417 520 509