



Neuren (NEU) - ASX Announcement

12 October 2015

## Neuren receives Notice of Allowance for new US patent covering the use of trofinetide to treat Rett syndrome

**Melbourne, Australia, 12 October 2015:** Neuren Pharmaceuticals (ASX: NEU) today announced that, following examination, the US Patent and Trademark Office has issued a Notice of Allowance for a new patent concerning the use of trofinetide to treat Rett syndrome. When it formally issues, the patent is expected to expire in January 2032.

Neuren is currently developing trofinetide as a new therapy for Rett syndrome and other neurological disorders. The Rett syndrome program has been granted Fast Track designation by the US Food and Drug Administration (FDA) and has orphan drug designation in both the United States and the European Union.

In the United States, trofinetide is currently covered by an issued composition of matter patent, which expires in 2022, with the potential to extend to 2026. In addition, orphan drug designation provides a market exclusivity period of 7 years following marketing authorization. The new patent will provide additional protection out to 2032.

Neuren has similar patent applications pending in other territories. Orphan drug designation in the European Union provides 10 years of market exclusivity following marketing authorization.

### About trofinetide

Trofinetide is a synthetic analogue of a naturally occurring neurotrophic peptide derived from IGF-1, a growth factor produced by brain cells. In animal models, trofinetide exhibits a wide range of important effects including inhibiting neuroinflammation, normalizing the role of microglia and correcting deficits in synaptic function. Trofinetide is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. The intravenous form of trofinetide is presently in a Phase 2 clinical trial in patients with moderate to severe traumatic brain injury. The oral form of trofinetide 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 Rett syndrome and Fragile X syndrome programs have also received Orphan Drug designation in the United States and the European Union.



## **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, trofinetide 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.*

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