



**Neuren (NEU) - ASX Announcement**

**22 June 2016**

## **Neuren receives grant of new Australian patent for trofinetide to treat Autism Spectrum Disorders**

**Melbourne, Australia, 22 June 2016:** Neuren Pharmaceuticals (ASX: NEU) today announced that IP Australia has issued a Notice of Grant for a new patent that covers the use of trofinetide for the treatment of Autism Spectrum Disorders, including Rett syndrome, Fragile X syndrome, Asperger syndrome and autism. Patent number AU2012209466 expires in January 2032.

The new patent derives from an international patent application filed in 2012. Neuren has patent applications pending in the United States, Europe, Canada, Japan, Brazil and Israel, all of which are derived from the same international application.

Neuren Executive Chairman Richard Treagus commented: "The grant of this patent is commercially important and timely for two reasons. Firstly, Neuren now has an issued patent that protects trofinetide for Rett syndrome and Fragile X syndrome in the Australian market. Secondly it is the first patent to be granted from a series of applications in the major pharmaceutical markets that cover the use of trofinetide broadly in Autism Spectrum Disorders until 2032."

Neuren is in Phase 2 development of trofinetide as a new therapy for Rett syndrome and Fragile X syndrome. The second Phase 2 trial in Rett syndrome, which is enrolling children and adolescents, is presently underway. Both the Rett syndrome and Fragile X syndrome programs have been granted Fast Track designation by the US Food and Drug Administration (FDA) and have orphan drug designation in both the United States and the European Union. Following marketing authorization, orphan drug designation provides a market exclusivity period of 7 years in the United States and 10 years in the European Union.

### **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, correcting deficits in synaptic function and regulating oxidative stress response. Trofinetide is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. The oral form of trofinetide is in Phase 2 development in Rett syndrome, Fragile X syndrome and concussion. The intravenous form of trofinetide is in Phase 2 development for moderate to severe traumatic brain injury. 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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