



**Neuren (NEU) – ASX Announcement**

**29 April 2021**

## **New patent granted to 2032 for Neuren’s trofinetide in Canada**

### **Highlights:**

- **First patent issued for trofinetide in Canada, covering treatment of Rett syndrome and autism spectrum disorders to Jan 2032**
- **Rett syndrome LAVENDER Phase 3 trial top-line results expected in Q4 2021**

**Melbourne, Australia:** Neuren Pharmaceuticals (ASX: NEU) has received confirmation that the Canadian Intellectual Property Office issued Neuren’s first patent in Canada. Patent number 2823218 covers the treatment of Rett syndrome and autism spectrum disorders using trofinetide. The patent term extends to January 2032, excluding any potential term extension.

Neuren’s US partner Acadia Pharmaceuticals (Nasdaq: ACAD) has an exclusive licence for the development and commercialisation of trofinetide in North America. Top-line results of the LAVENDER Phase 3 trial of trofinetide for Rett syndrome are expected in Q4 2021.

The development and commercialisation of trofinetide in North America is fully funded by Acadia and Neuren is eligible to receive potential milestone payments of up to US\$455 million, tiered escalating double digit percentage royalties on net sales of trofinetide in North America, and one third of the market value of any Rare Pediatric Disease Priority Review Voucher, if awarded by the FDA upon approval of a New Drug Application for trofinetide. In addition, Neuren has free and full access to all data for use in countries outside North America.

Patents originating from the same international application have now been issued in the United States, Europe, Japan, Australia, Israel and Canada. Examination is continuing in Brazil.

### **Contact:**

Jon Pilcher, CEO: [jpilcher@neurenpharma.com](mailto:jpilcher@neurenpharma.com); +61 438 422 271

### **ASX Listing Rules information**

This announcement was authorized to be given to the ASX by the board of directors of Neuren Pharmaceuticals Limited, Suite 201, 697 Burke Road, Camberwell, VIC 3124



## **About Neuren**

Neuren is developing two new drug therapies to treat multiple serious neurological disorders that emerge in early childhood, none of which have any approved medicines.

The lead drug compound, trofinetide, is currently in a Phase 3 clinical trial for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. Both programs have been granted Fast Track designation by the US Food and Drug Administration (FDA). Neuren has granted an exclusive licence to ACADIA Pharmaceuticals Inc. for the development and commercialisation of trofinetide in North America, while retaining all rights outside North America.

Neuren plans to initiate Phase 2 trials of its second drug candidate, NNZ-2591, for each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome in 2021. Neuren is also preparing for a Phase 2 trial in Prader-Willi syndrome.

Because of the urgent unmet need, five programs have been granted “orphan drug” designation in both the United States and the European Union, a designation that provides incentives to encourage therapies for rare and serious diseases.

## ***Forward-looking Statements***

*This 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.*