



Neuren (NEU) – ASX Announcement

16 September 2021

New patent granted to 2032 for Neuren’s trofinetide in Brazil

Highlights:

- **First patent issued for trofinetide in Brazil, 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 Brazilian patent office issued a notice of allowance for Neuren’s first patent in Brazil, which covers the treatment of Rett syndrome and autism spectrum disorders using trofinetide.

The term of the patent, titled “Use of glycyl-l-2-methylprolyl-l-glutamic acid and analogues thereof for the treatment of autism spectrum disorders” extends to January 2032.

Neuren’s US partner Acadia Pharmaceuticals (Nasdaq: ACAD) has an exclusive licence for the development and commercialisation of trofinetide in North America. Neuren retains all rights outside North America and has free and full access to all data for use in countries outside North America. Top-line results of the LAVENDER Phase 3 trial of trofinetide for Rett syndrome are expected in Q4 2021.

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

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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 compound, trofinetide, is currently in a Phase 3 clinical trial for Rett syndrome with top-line results expected in Q4 2021 and has completed a Phase 2 clinical trial in Fragile X syndrome. Both programs have Fast Track designation from 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 is preparing 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 H2 2021. Neuren is also planning a Phase 2 trial in Prader-Willi syndrome.

Recognising the urgent unmet need, all six programs have been granted “orphan drug” designation in the United States. Orphan drug designation provides incentives to encourage development of 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.

ASX Listing Rules information

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