

Neuren (NEU) – ASX Announcement

5 February 2026

Rare Pediatric Disease Priority Review Voucher program reauthorized by US Congress to September 2029

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) notes that on 3 February 2026 EST the United States (US) Congress reauthorized the Rare Pediatric Disease Priority Review Voucher (PRV) program to 30 September 2029.

Neuren CEO Jon Pilcher commented: “We welcome the reauthorization of the Rare Pediatric Disease PRV program, an important incentive that supports the development of urgently needed therapies for children suffering with rare diseases and enables companies like Neuren to advance innovation in these underserved pediatric populations.”

The Rare Pediatric Disease PRV program provides for the award of a voucher to drug developers that receive US Food and Drug Administration (FDA) approval for a drug for a designated rare pediatric disease. The voucher entitles the holder to priority review of a different drug or may be transferred or sold to another drug developer. Most recently in January 2026, a drug developer announced the sale of a voucher for US\$200m.

Neuren currently holds Rare Pediatric Disease designations for NNZ-2591 in Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome. FDA approval of NNZ-2591 in any one of these designated rare pediatric diseases would qualify Neuren for a voucher, of which Neuren would retain 100% ownership and proceeds of any sale.

About Neuren

Neuren is developing new drug therapies to treat multiple serious neurological disorders that emerge in early childhood and have no or limited approved treatment options.

DAYBUE® (trofinetide) and DAYBUE STIX (trofinetide) are approved by the US Food and Drug Administration (FDA) for the treatment of Rett syndrome. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren’s second drug candidate, NNZ-2591, is in development for multiple neurodevelopmental disorders, with positive results achieved in Phase 2 clinical trials in Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome. Recognising the urgent unmet need, each program has been granted “orphan drug” designation in the United States and the European Union. Orphan drug designation provides incentives to encourage development of therapies for rare and serious diseases.



Contact:

investorrelations@neurenpharma.com

Jon Pilcher, CEO: +61 438 422 271

ASX Listing Rules information

This announcement was authorized to be given to the ASX by the Board of Neuren Pharmaceuticals Limited, Suite 1.01, 117 Camberwell Road, Hawthorn East, VIC 3123

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.