



Neuren (NEU) – ASX Announcement

29 September 2026

Trofinetide US patent protections extended to March 2041

Highlights:

- Acadia Pharmaceuticals announced allowance of US patent covering weight-banded dosing of trofinetide, extending US patent protections to March 2041

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported that its partner for trofinetide, Acadia Pharmaceuticals (Nasdaq: ACAD), announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application No. 17/590,496, titled "Methods and Compositions for Treatment of Rett Syndrome." The Notice of Allowance indicates that the USPTO has determined that the application meets the requirements for patentability, and the patent is expected to issue following completion of standard administrative steps. Acadia's announcement can be accessed in the Investors section of the Acadia website www.acadia.com.

The patent application covers weight-banded dosing of trofinetide for the treatment of Rett syndrome. Following issuance and including six months of pediatric exclusivity, the patent is expected to provide protection for trofinetide in the United States through March 28, 2041, extending patent protections by almost five years. Trofinetide is also protected by a method of use patent for the treatment of Rett syndrome, which expires in July 2036.

The Notice of Allowance relates to the weight-banded dosing regimen used for trofinetide, which is marketed in the United States as DAYBUE® and DAYBUE® STIX for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

About Neuren

Neuren Pharmaceuticals is developing new drug therapies to treat multiple serious neurological disorders caused by genetic abnormalities or brain injury, that have no or limited approved treatment options. Neuren's therapies target the critical role of Insulin-like growth factor 1 (IGF-1) in the brain, using orally administered analogs of naturally occurring peptides.

DAYBUE® (trofinetide) oral solution is approved by the US Food and Drug Administration (FDA), Health Canada and the Ministry of Health in Israel and DAYBUE STIX (trofinetide) powder is approved by the FDA for the treatment of Rett syndrome. Neuren has granted an exclusive worldwide license to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren's investigative drug candidate, NNZ-2591 (ercanetide), is in clinical development as an oral solution treatment for multiple neurodevelopmental disorders, including Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome. Each of these programs has been granted "orphan drug" designation in the United States and the European Union as well as Fast Track and Rare Pediatric Disease designations from the FDA. Neuren is also developing NNZ-2591 for the treatment of hypoxic ischemic encephalopathy (HIE), a serious condition caused by brain injury before or shortly after birth.



Currently, Neuren is conducting a Phase 3, randomized, double-blind, placebo-controlled clinical trial (“Koala”) evaluating the safety and efficacy of NNZ-2591 in children aged 3 to 12 years with Phelan-McDermid syndrome and a 52-week open-label extension study.

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ASX Listing Rules information

This announcement was authorized to be given to the ASX by the CEO 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.