Neuren (NEU) – ASX Announcement **8 April 2026**

DAYBUE® STIX now broadly available in US for treatment of Rett syndrome

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) is pleased to advise that its partner Acadia Pharmaceuticals (Nasdaq: ACAD) today announced DAYBUE® STIX (trofinetide) for oral solution, a dye- and preservative-free powder formulation of trofinetide, is now broadly available in the United States for the treatment of Rett syndrome in adults and pediatric patients two years of age and older. The new formulation was approved by the US Food and Drug Administration (FDA) in December 2025 and launched in the US on a limited basis in Q1 2026.

DAYBUE STIX is a for oral solution powder that caregivers can mix with a variety of water-based liquids such as juice, tea, lemonade, limeade, or liquid hydration so that caregivers have the ability to customize to their loved ones' taste. The product comes in individual packets that are easily portable.

Acadia noted that initial feedback from a small group of caregivers following the limited launch revealed that more than 80% of early users reported satisfaction with DAYBUE STIX, highlighting the added flexibility and portability of this new formulation.

The importance of flexible, patient-centered approaches was reinforced in a recent publication of expert recommendations for real-world use of trofinetide in Rett syndrome. A steering group comprised of experts based at International Rett Syndrome Foundation (IRSF)-designated centers of excellence (COEs) reached consensus recognizing trofinetide oral solution as part of the standard of care for individuals with Rett syndrome. They also aligned on key real-world considerations such as early initiation and sustained use over time. The recommendations also reflect shared perspectives on the need for individualized decision making in clinical practice to help optimize outcomes for patients, families, and caregivers.[1]

“The availability of DAYBUE STIX gives us an additional, flexible way to administer trofinetide, which allows us more options to address unique patient and caregiver needs,” said Arthur Beisang, M.D., Department of Pediatrics, Gillette Children's Specialty Healthcare, Saint Paul, Minn. “This patient-centered approach aligns with recently published expert consensus recommendations, which advocate for the integration of trofinetide as part of the standard of care and comprehensive Rett syndrome management. This new option provides additional customization, supporting individualized care for people with Rett syndrome.”

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

[1] *Prange EO, Beisang A, Pehlivan D, et al. Expert Consensus on Real-World Use of Trofinetide for Rett Syndrome Using a Modified Delphi Method. Ann Child Neurol. 2026; 4:38-51*

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 commercialization of trofinetide.

Neuren's second drug candidate, NNZ-2591, is in clinical development as an oral solution treatment for multiple neurodevelopmental disorders, with positive results achieved in Phase 2 clinical trials in 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 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.