Neuren (NEU) – ASX Announcement **25 August 2026**

European Commission grants marketing authorisation for DAYBU® (trofinetide)

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) is pleased to advise that its exclusive global licensee for trofinetide, Acadia Pharmaceuticals (Nasdaq: ACAD), announced the European Commission has granted marketing authorization for DAYBU (trofinetide) for the treatment of neurobehavioral symptoms of Rett syndrome in adults and pediatric patients aged five years and older. DAYBU is the first and only treatment approved for Rett syndrome in the European Union (EU). Acadia's announcement can be accessed in the Investors section of the Acadia website www.acadia.com.

Neuren CEO Jon Pilcher commented: "We are delighted for the Rett syndrome community in Europe, who, until now, have had no approved treatment for this devastating condition. The European Commission's approval of DAYBU is particularly rewarding for Neuren given our long-standing commitment to developing therapies for serious neurological disorders with profound unmet need. We look forward to seeing our partner Acadia make DAYBU available for Rett patients and families in Europe.

With this approval, DAYBU is authorized to be marketed in all 27 EU member states, as well as Iceland, Liechtenstein, and Norway.

Acadia has previously stated that commercial launch in Germany is anticipated in early Q4 2026. Under the licence agreement, for Europe, Neuren is entitled to receive US$35 million following first commercial sale, potential sales milestone payments of up to US$170 million on achievement of escalating annual net sales thresholds, and tiered royalties from mid-teens to low-20s % of net sales.

Trofinetide is not approved for sale in Australia.

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. DAYBU® (trofinetide) is approved by the European Commission for the treatment of neurobehavioral symptoms 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.

Investor contact:
Jon Pilcher, CEO & Managing Director
+61 438 422 271
investorrelations@neurenpharma.com

Media Contact:
Monsoon Communications
Rudi Michelson
rudim@monsoon.com.au

Investor Hub

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.