Neuren (NEU) – ASX Announcement **15 January 2025**

Trofinetide marketing application submitted in Europe

Highlights:

- **Marketing Authorization Application for trofinetide in Rett syndrome submitted to European Medicines Agency by Acadia, with potential for approval in Q1 2026**
- **Acadia anticipates initiating Managed Access Programs in Europe in Q2 2025**

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today announced that its partner Acadia Pharmaceuticals (NASDAQ: ACAD) has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for trofinetide for the treatment of Rett syndrome in adults and pediatric patients two years of age and older. Acadia anticipates potential approval in Q1 2026. If granted marketing authorization, trofinetide will be the first and only approved therapy for Rett syndrome in the European Union. Acadia also anticipates initiating Managed Access Programs in Europe in the second quarter of 2025.

DAYBUE™ (trofinetide) is already approved in the United States and Canada for Rett syndrome.

Neuren CEO Jon Pilcher commented: "We are pleased to see the achievement of this very important milestone towards potentially bringing trofinetide to the Rett community in Europe."

Acadia's announcements today can be viewed via the following links:
https://ir.acadia.com/news-releases/news-release-details/acadia-pharmaceuticals-submits-marketing-authorization
https://ir.acadia.com/news-releases/news-release-details/acadia-pharmaceuticals-provides-business-and-pipeline-updates

Under the worldwide licence agreement with Acadia, Neuren is eligible to receive milestone payments and royalties related to development and commercialization of trofinetide outside North America, as detailed in the table below.

Trofinetide	Payment
Upon 1st commercial sale for Rett in Europe	US$35m
Upon 1st commercial sale for Rett in Japan	US$15m
Upon 1st commercial sale for second indication in Europe	US$10m
Upon 1st commercial sale for second indication in Japan	US$4m
Total development milestones	**US$64m**
Europe	Up to US$170m
Japan	Up to US$110m
Rest of World	Up to US$83m
Total sales milestones on achievement of escalating annual net sales thresholds	**Up to US$363m**
Tiered royalties on net sales	**Mid-teen to low twenties per cent**

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. Recognising the urgent unmet need, all 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.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) and Health Canada 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 Phase 2 development for multiple neurodevelopmental disorders, with positive results achieved in Phase 2 clinical trials in Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome.

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ASX Listing Rules information

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

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.