

### Neuren (NEU) – ASX Announcement

8 May 2025

# DAYBUE<sup>™</sup> Q1 2025 net sales US\$84.6 million up 11% from Q1 2024

Highlights:

- Q1 2025 DAYBUE<sup>™</sup> (trofinetide) net sales of US\$84.6 million, up 11% from Q1 2024
- Record number of unique patients received shipments, up 4% from Q4 2024
- Neuren's Q1 2025 royalty income was A\$13.5 million, up 17% from Q1 2024
- Acadia retained full year 2025 DAYBUE US net sales guidance of US\$380 405 million, implying full year 2025 US royalty income for Neuren of A\$62 67 million
- Marketing approval in Europe anticipated in Q1 2026, first shipment of DAYBUE to Europe was made in April 2025 under a Managed Access Program
- Orphan Drug designation granted in Japan
- Distribution agreements now in place to facilitate named patient supply in other regions including Latin America, Middle East and Asia Pacific
- Neuren cash and short-term investments \$341 million at 31 March 2025
- Neuren is presenting at Macquarie Australia Conference on 8 May 2025

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported highlights from the Q1 2025 financial results announcement and conference call of its partner Acadia Pharmaceuticals (Nasdaq: ACAD). Acadia announced Q1 2025 net sales of DAYBUE<sup>™</sup> (trofinetide) in the United States (US) of US\$84.6 million, up 11% on Q1 2024 and retained its full year 2025 US net sales guidance of US\$380 - 405 million.

The number of unique patients receiving a DAYBUE shipment reached a record high of 954 in Q1 2025, an increase of 4% from Q4 2024. Discontinuations were down 35% compared to Q4 2024 and down 66% compared with Q1 2024. The persistency rate remains steady above 50% at 12 months. 65% of active patients have now been on therapy for 12 months or longer.

Consistent with Acadia's previous disclosures at its CY2024 full year financial results conference call and consistent with the prior year, Q1 2025 DAYBUE net sales were lower than Q4 2024 due mainly to the typical seasonal pattern of refills brought forward from January to December and a small reduction in average net price per bottle as a result of US Medicare Part D redesign. Acadia expects DAYBUE unique patients, volumes and net sales in the US to increase through 2025.

There is substantial potential for future growth in the US with two-thirds of the 5,500 to 5,800 diagnosed Rett patients yet to try DAYBUE. Acadia has now completed expansion of its field force by ~30% to further accelerate growth.

Acadia's full year 2025 DAYBUE net sales guidance is for the US only. Acadia is anticipating approval of the marketing application for Europe in Q1 2026 and continues to build EU leadership and launch teams.



In the meantime, the first shipment of DAYBUE was made to a Rett syndrome patient in Germany in April under a managed access program. In Japan, trofinetide has now received Orphan Drug Designation and Acadia is on track to commence the planned clinical trial in Japan in Q3 2025. Acadia has also entered into distribution agreements to facilitate named patient supply in other regions including Latin America, Middle East and Asia Pacific.

Anticipated royalties to Neuren are:

- A\$13.5 million for Q1 2025 (assuming exchange rate of 0.625), up 17% on Q1 2024, the prior corresponding period
- Between A\$62 million and A\$67 million in the US for the full year 2025 (assuming Acadia guidance is met and exchange rate of 0.65)



\* Assuming Acadia DAYBUE US net sales guidance of US\$380 – 405m is met and AUDUSD of 0.65



## DAYBUE US Net Sales (US\$m)



Neuren had total cash and short-term investments at 31 March 2025 of A\$341 million, following receipt from Acadia in Q1 2025 of A\$176 million across royalties, sales milestone payment and share of Priority Review Voucher sale proceeds.

Today Neuren will participate in the Macquarie Australia Conference for the first time.

Acadia's Q4 and full year earnings conference call and presentation can be accessed in the Investors section of the Acadia website <u>www.acadia.com</u>.

#### **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<sup>™</sup> (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 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.