

Neuren (NEU) – ASX announcement

27 July 2023

Neuren receives US\$100 million initial payment for expanded DAYBUE™ agreement

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported that it has received the up-front payment of US\$100 million that was earned following the recent expansion of its partnership with Acadia Pharmaceuticals (NASDAQ: ACAD) for trofinetide (marketed in the United States as DAYBUE™) to a worldwide exclusive licence.

DAYBUE is the first approved treatment for Rett syndrome and was launched in the US by Acadia in April 2023. Acadia recently provided very encouraging early insights into the US launch of DAYBUE, expecting net sales of US\$21-23 million in Q2 2023 and US\$45-55 million in Q3 2023.

Under the expanded agreement, the existing future payments to Neuren relating to trofinetide in North America remain unchanged, at up to US\$350 million milestone payments on achievement of escalating thresholds of annual net sales, plus tiered royalties ranging from 10% to 15% of net sales, plus one third of the value realized by Acadia from the Rare Pediatric Disease Priority Review Voucher that was awarded on FDA approval of DAYBUE.

For trofinetide outside North America, in addition to the US\$100 million up-front payment, Neuren is eligible to receive potential first commercial sale milestone payments of up to US\$64 million, plus up to US\$363 million milestone payments on achievement of escalating thresholds of annual net sales, plus tiered royalties ranging from mid-teens to early 20s % of net sales.

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.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren is conducting Phase 2 trials of its second drug candidate, NNZ-2591, for each of Phelan-McDermid syndrome, Angelman syndrome, Pitt Hopkins syndrome and Prader-Willi syndrome.

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.

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ASX Listing Rules information

This announcement was authorized to be given to the ASX by the board of directors 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.