Neuren (NEU) - ASX Announcement **13 September 2021**

NEUREN COMPLETES PLACEMENT TO ACCELERATE NNZ-2591 ACROSS 4 INDICATIONS

Highlights:

- **Placement of A$20 million strongly supported by institutional investors in Australia and overseas at $2.05 per share**
- **Cornerstone support from leading institutional healthcare investors, with total applications from new and existing shareholders far exceeding A$20 million**
- **Share Purchase Plan at $2.05 per share for eligible shareholders in Australia and NZ to raise up to a further A$2m**
- **Funds raised enable Neuren to accelerate NNZ-2591 towards Phase 3 in four indications:**
    - **Phase 2 clinical trial for Prader-Willi syndrome, following recent grant of Orphan Drug designation by FDA**
    - **Phase 3 preparation in parallel with Phase 2 trials – applicable across Prader-Willi, Phelan-McDermid, Angelman and Pitt Hopkins syndromes**
- **Transforming events in Q4 2021 and series of catalysts through to 2023:**
    - **LAVENDER Phase 3 trial of trofinetide in Rett syndrome top-line results in Q4 2021; positive results would enable New Drug Application to FDA and partnering in Europe and Asia in 2022**
    - **Preparing to commence Phase 2 trials for NNZ-2591 in Phelan-McDermid, Angelman and Pitt Hopkins syndromes in H2 2021, with results in H2 2022**
    - **Prader-Willi syndrome Phase 2 trial to commence mid-2022, results in 2023**
    - **Four Investigational New Drug (IND) Applications to FDA for NNZ-2591**
- **Potential for Neuren to receive revenue over 2022 and 2023 for Rett syndrome in the US alone of A$111 million plus royalties on net sales**
- **Pro-forma cash of $37 million at 31 July 2021, assuming full subscription of placement and SPP**

Melbourne, Australia, 13 September 2021: Neuren Pharmaceuticals (ASX: NEU) (**Company** or **Neuren**) is pleased to announce that it has completed a placement of new shares to institutional and sophisticated investors at A$2.05 per share, providing additional capital of A$20 million (**Placement**). The Placement was strongly supported by institutions in Australia and overseas, with applications from new investors and existing shareholders far exceeding A$20 million. The Company also intends to offer a Share Purchase Plan at the same share price as the Placement, capped at A$2 million, to

existing eligible shareholders in Australia and New Zealand (**SPP**). Assuming full subscription of the Placement and SPP, Neuren's pro-forma cash is $37 million at 31 July 2021.

The Placement funds will accelerate the development and increase the value of NNZ-2591 for four neurodevelopmental disorders, by enabling a Phase 2 clinical trial in Prader-Willi syndrome and the foundational work to be ready for Phase 3 development across Prader-Willi, Phelan-McDermid, Angelman and Pitt Hopkins syndromes. NNZ-2591 now has Orphan Drug designation from the US Food and Drug Administration (**FDA**) for all four disorders following the recent grant for Prader-Willi syndrome.

Neuren has a series of catalysts for trofinetide and NNZ-2591 from now through to 2023, with transforming events before the end of 2021. Top-line results from the LAVENDER Phase 3 trial of trofinetide in Rett syndrome are due in Q4 2021. Positive results would enable Neuren's US partner Acadia Pharmaceuticals to submit a New Drug Application (**NDA**) to the FDA and enable Neuren to engage commercial partners for Europe and Asia in 2022. In parallel, Neuren is preparing to commence Phase 2 trials for NNZ-2591 in Phelan-McDermid, Angelman and Pitt Hopkins syndromes in H2 2021, with results in H2 2022. The Prader-Willi syndrome Phase 2 trial is planned to commence in mid-2022 after meeting with the FDA and submitting an Investigational New Drug (IND) application, targeting results in 2023. An IND application was recently submitted to the FDA for Angelman syndrome, with applications imminent for each of Phelan-McDermid and Pitt Hopkins syndromes.

If a NDA is approved by the FDA and trofinetide is launched in the US, Neuren would earn revenue over 2022 and 2023 for Rett syndrome in the US alone of A$111 million plus double-digit percentage royalties on net sales. This assumes a USD/AUD exchange rate of 0.75 and that Neuren receives US$33 million as its share of the market value of a Rare Pediatric Disease Priority Review Voucher if awarded on approval of the NDA.

Neuren Non-Executive Chair Patrick Davies said: "We are highly encouraged to have received such strong support from existing and new investors for the Placement, which enables Neuren to accelerate the delivery of substantial value for all shareholders. We are now in a very strong position to capitalise fully on the transforming events expected in the coming months."

Neuren CEO Jon Pilcher commented: "This additional funding enables Neuren to accelerate and optimise the crystallisation of value for NNZ-2591. We are excited as we approach the Phase 3 results for trofinetide in Rett syndrome before the end of the year, but equally excited about the prospects for NNZ-2591 in each of Prader-Willi, Phelan-McDermid, Angelman and Pitt Hopkins syndromes for which we estimate the total number of patients is five times Rett syndrome. To date in 2021 we have achieved all our targeted milestones and we now have an even stronger series of future catalysts to maintain the momentum."

As announced on Friday 10 September, Neuren will host an investor briefing at 9.00 AEST on Monday 13 September 2021. A hyperlink to register for the briefing is contained in the 10 September announcement.

Use of Funds

Neuren will use the proceeds received from the Placement to:

- Pursue development of NNZ-2591 for Prader-Willi syndrome
    - File IND application and commence Phase 2 trial in mid-2022, targeting results in 2023
- Complete foundational work for NNZ-2591 Phase 3 development across Phelan-McDermid, Angelman, Pitt Hopkins and Prader-Willi syndromes
    - Non-clinical toxicology studies for chronic dosing in Phase 3 and commercial use
    - Manufacturing scale-up and commercial product presentation
    - Validation of efficacy measures

Placement details

Under the terms of the Placement, Neuren secured firm commitments for, and proposes to issue, a total of 9.8 million new fully paid ordinary shares (**Placement Shares**) at a price of A$2.05 per share, which represents a discount of 8.9% to the last close of A$2.25 on 9 September 2021.

The Placement is being conducted under Neuren's existing placement capacity pursuant to ASX Listing Rule 7.1A. Issuance of the Placement Shares is expected to occur on Friday 17 September 2021. Placement Shares will rank equally with existing ordinary shares on issue with effect from their date of issue.

Bell Potter Securities Limited acted as lead manager and bookrunner to the Placement, which was not underwritten. WG Partners acted as co-lead manager to the Placement.

Share Purchase Plan

Neuren will conduct an offer of new fully paid ordinary shares under a non-underwritten SPP (**SPP Shares**) to existing shareholders in the Company with a registered address in Australia and New Zealand as at 7:00pm (Sydney, Australia time) on Friday 10 September 2021 (**Eligible Shareholders**).

The SPP will provide each Eligible Shareholder with the opportunity to apply for up to A$30,000 of SPP Shares at the same price as for the Placement Shares. The SPP is capped at A$2 million. The Company reserves the right to scale back applications at its discretion if applications in excess of the SPP cap of A$2 million are received and accept oversubscriptions in the event that applications for SPP Shares exceed A$2 million. **In the event of a pro-rated scale back, the Company intends to prioritise applications based on the number of shares that are held by applicants as at the SPP Closing Date rather than as at the SPP Record Date.**

An indicative timetable for the SPP is set out as follows (**Timetable**):

Event	Date (and time if relevant)
SPP Record Date	7.00pm AEST, Friday, 10 September 2021
SPP Opening Date	Friday, 17 September 2021
SPP Closing Date	5.00pm AEST, Friday, 1 October 2021
Results of SPP announced	Wednesday, 6 October 2021
Allotment and issue of SPP Shares	Friday, 8 October 2021

Note: All times are in Australian Eastern Standard Time (**AEST**) which is the time applicable in Melbourne, Victoria.

This Timetable is indicative only and subject to change. The Company may vary these dates in their discretion, including by bringing forward or extending the SPP Closing Date. In the event of any such variation, the Company will lodge the varied timetable with the ASX.

SPP Shares will rank equally with existing ordinary shares on issue with effect from their date of issue. The SPP booklet containing further details of the SPP will be released separately to all Eligible Shareholders.

About Neuren

Neuren is developing two new drug therapies to treat multiple serious neurological disorders that emerge in early childhood, none of which have any approved medicines.

The lead compound, trofinetide, is currently in a Phase 3 clinical trial for Rett syndrome with top-line results expected in Q4 2021 and has completed a Phase 2 clinical trial in Fragile X syndrome. Both programs have Fast Track designation from the US Food and Drug Administration (FDA). Neuren has granted an exclusive licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide in North America, while retaining all rights outside North America.

Neuren is preparing to initiate Phase 2 trials of its second drug candidate, NNZ-2591, for each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome in H2 2021. Neuren is also planning a Phase 2 trial in Prader-Willi syndrome.

Recognising the urgent unmet need, all six 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.