



Neuren (NEU) - ASX Announcement

29 June 2017

Neuren secures funding for key preparatory activities for Rett syndrome Phase 3 trial

Highlights:

- **Funding enables key activities on the critical path for commencing a Phase 3 trial in Rett syndrome:**
 - **Conduct meeting with the US Food and Drug Administration (FDA) Division of Neurology in Q3 2017 to discuss the remaining development for Rett syndrome**
 - **Conclude optimisation of drug substance manufacturing process for commercial supply**
 - **Conclude stability testing and analytical validation of to-be-marketed liquid drug formulation**
 - **Conduct non-clinical toxicity study in second species, required for Phase 3 trial with longer dosing and to support a New Drug Application to the FDA**
- **Placement of new ordinary shares raising A\$11.5 million at 6.2 cents per share anchored by A\$10 million from UK fund Lanstead Capital, with supporting investments from Rettsyndrome.org and Neuren directors and management**
- **Lanstead investment structured to enable Neuren to share in the benefit from potential increases in Neuren's share price over the next 18 months**

Melbourne, Australia, 29 June 2017: Neuren Pharmaceuticals (ASX: NEU) today announced that it has secured funding to enable initiation of key activities on the critical path for commencing a Phase 3 trial in Rett syndrome. The placement of new ordinary shares raising A\$11.5 million at 6.2 cents per share is anchored by A\$10 million from UK fund Lanstead Capital, with supporting investments from Rettsyndrome.org and Neuren's directors and management. The volume weighted average price at which Neuren's shares were traded in the 10 days ending 26 June 2017 was 6.0 cents.

Neuren plans to meet with the US Food and Drug Administration (FDA) Division of Neurology in the third quarter of 2017 to discuss the remaining development for trofinetide to treat Rett syndrome, including the Phase 3 trial design.

In parallel with the FDA interactions, Neuren can now initiate the following key manufacturing and non-clinical activities that are required to be completed before a Phase 3 trial can commence:

- **Conclude optimisation of the drug substance manufacturing process for commercial supply**
- **Conclude stability testing and analytical validation of the new to-be-marketed liquid drug formulation**



- Conduct non-clinical toxicity study in a second species, which is required for a Phase 3 trial with longer dosing and subsequently to support a New Drug Application to the FDA

The cash flow for these activities will occur in the second half of 2017 and the first half of 2018.

Neuren's Executive Chairman Richard Treagus commented: "This is a very important financing for Neuren and the Rett syndrome community. We greatly appreciate the continuing strong partnership with Rettsyndrome.org. We are also pleased to have Lanstead as a new supportive institutional shareholder, with an arrangement that enables Neuren to benefit if we achieve share price appreciation. We can now focus on our meeting with the FDA and the preparations for a Phase 3 trial."

Placement details

Neuren will receive A\$3 million in July 2017, comprising A\$1.5 million from Lanstead and A\$1.5 million from Rettsyndrome.org and Neuren's directors and management.

The remaining A\$8.5 million from Lanstead will be invested in a Sharing Agreement with Lanstead, which enables Neuren to secure much of the potential upside from anticipated near term news flow. The Sharing Agreement provides that Neuren's economic interest will be determined and payable in 18 monthly settlements as measured against a benchmark price of 8.86 cents per share (Benchmark Price).

If the measured share price exceeds the Benchmark Price, for that month, Neuren will receive more than 100 per cent of the monthly settlement due on a pro rata basis. Importantly, there is no upper limit on the additional funds receivable by Neuren as part of the monthly settlements. Should the measured share price be below the Benchmark Price, Neuren will receive less than 100 per cent of the monthly settlement on a pro rata basis. In no event would a decline in the share price result in any increase in the number of shares received by Lanstead or any other benefit accruing to Lanstead. The amount of each settlement is dependent on the volume weighted average price at which Neuren's shares are traded in the 5 days preceding the settlement (VWAP).

If the VWAP over the 18 month period is equal to the Benchmark Price, Neuren will receive A\$8.5 million in total. If the VWAP is higher than the benchmark price, Neuren will receive proportionately more than A\$8.5 million, with no upper limit. If the VWAP is lower than the benchmark price, Neuren will receive proportionately less than A\$8.5 million.

185.5 million ordinary shares will be issued, comprising 161.3 million to Lanstead (A\$10 million at 6.2 cents per share) and 24.2 million to Rettsyndrome.org and Neuren's directors and management (A\$1.5m at 6.2 cents per share). The issue of 12.3 million of those shares (A\$760,000 at 6.2 cents per share) to directors will be subject to shareholder approval. In consideration of the value sharing agreement with Lanstead, 8.1 million additional ordinary shares will be issued to Lanstead, which is 5% of the shares issued to Lanstead in respect of the A\$10 million investment.



About trofinetide

Trofinetide is a synthetic analogue of a naturally occurring neurotrophic peptide derived from IGF-1, a growth factor produced by brain cells. In animal models, trofinetide exhibits a wide range of important effects including inhibiting neuroinflammation, normalizing the role of microglia, correcting deficits in synaptic function and regulating oxidative stress response. Trofinetide is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. The most advanced program is for Rett syndrome, supported by rettsyndrome.org. Both the Rett syndrome and Fragile X syndrome programs have been granted Fast Track designation by the US Food and Drug Administration (FDA) and have orphan drug designation in both the United States and the European Union. Following marketing authorization, orphan drug designation provides a market exclusivity period of 7 years in the United States and 10 years in the European Union.

About Neuren

Neuren Pharmaceuticals Limited (Neuren) is a biopharmaceutical company developing new therapies for brain injury, neurodevelopmental and neurodegenerative disorders. The novel drugs target chronic conditions as well as acute neurological injuries. Neuren presently has a clinical stage molecule, trofinetide in Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development.

Forward-looking Statements

This ASX-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.

For more information, please contact:

Dr Richard Treagus, Executive Chairman: rtreagus@neurenpharma.com ; +61 417 520 509