Neuren provides update on Fragile X and “INTREPID” trials

Melbourne, Australia, 29 September 2015: Neuren Pharmaceuticals (ASX: NEU) today reported the completion of the last subject visit in its Phase 2 clinical trial of trofinetide in Fragile X syndrome. Neuren remains on track to release top-line results from the trial in December 2015, as previously announced.

Only 8 more subjects are required to complete the target enrolment of 260 subjects in Neuren’s Phase 2 trial of trofinetide in moderate to severe traumatic brain injury (the “INTREPID2566” trial). The trial involves treatment with trofinetide or placebo in hospital for 72 hours and follow-up assessments for up to 3 months after randomization. Results from the trial are currently expected to be available in early 2016. Neuren will be able to confirm the timing of the release of top-line results after the last subject has been enrolled.

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 and correcting deficits in synaptic function. In November 2014, Neuren announced top-line results from its Phase 2 clinical trial in Rett syndrome, which successfully demonstrated clinical benefit from treatment with trofinetide. The benefit observed in the trial encompassed many of the core symptoms of Rett syndrome and was observed in both clinician and caregiver assessments.

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 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.

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