



Neuren (NEU) - ASX Announcement

20 July 2017

Neuren granted Type B Meeting with FDA for Rett syndrome

Melbourne, Australia, 20 July 2017: Neuren Pharmaceuticals (ASX: NEU) today announced that the US Food and Drug Administration (FDA) has granted its request for an End-of-Phase 2 meeting to discuss the remaining development plan for trofinetide in Rett syndrome. The FDA has scheduled a face-to-face Type B meeting in October 2017.

Neuren's Executive Chairman Richard Treagus commented: "We are pleased to have received confirmation of this important End-of-Phase 2 meeting. We and our clinical experts are looking forward to presenting and discussing with the FDA our Phase 3 plans."

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