



Neuren (NEU) - ASX Announcement

2 April 2020

First patent in Israel granted for trofinetide

Melbourne, Australia, 2 April 2020: Neuren Pharmaceuticals (ASX: NEU) today announced that a new patent has been granted by the Israel Patent Office covering trofinetide to treat Rett syndrome, Fragile X syndrome and autism. This first patent for trofinetide in Israel expires in 2032, with the potential for patent term extension of up to 5 years.

Patents derived from the same international patent application have previously been granted in the US, Europe, Japan and Australia, with applications still under examination in Brazil and Canada.

Neuren's commercial partner for North America, ACADIA Pharmaceuticals, is currently funding and executing the Phase 3 development of trofinetide for Rett syndrome in the US, with results expected in 2021 and potential marketing approval in 2022. Neuren has free and full access to utilise the US regulatory package for registration and commercialization outside North America, as well as receiving a significant share of the value in North America through double digit percentage royalties on all sales, milestone payments of up to US\$455 million and one third of the market value of a Priority Review Voucher.

About Neuren

Neuren is developing new therapies for neurodevelopmental disorders with high unmet need, utilizing synthetic analogs of neurotrophic peptides that occur naturally in the brain. Trofinetide is currently in a Phase 3 clinical trial for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. The programs have each received Fast Track designation by the US Food and Drug Administration and Orphan Drug designation in both the United States and the European Union. Neuren has granted an exclusive license to ACADIA Pharmaceuticals Inc. for the development and commercialization of trofinetide in North America, whilst retaining all rights outside North America. Neuren is advancing the development of NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndromes, each of which has received Orphan Drug designation in the United States.

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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.