



Neuren Receives Fast Track Designation for NNZ-2566 in Rett Syndrome

Australia, 5 June 2013: Neuren Pharmaceuticals Ltd. (ASX:NEU) is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Neuren's program to develop NNZ-2566 in Rett Syndrome. Fast Track designation is designed to expedite the development and review of important new medicines that are intended to treat serious diseases and fill unmet medical needs.

Neuren initiated a Phase II clinical trial in Rett Syndrome at Texas Children's Hospital/Baylor College of Medicine in April 2013. The trial will enrol up to 60 adolescent and adult subjects, allowing for some early discontinuations, in order to meet a target of 48 who complete all scheduled doses and assessments. Enrolment and follow-up are expected to be complete in 1H 2014 with top line results announced in 2H 2014.

Larry Glass, Neuren's CEO and Managing Director, remarked, "This is an important and welcomed decision by the FDA. It will assist Neuren in accelerating the development of a treatment for the core features of Rett Syndrome and is recognition of the critical unmet needs of these girls and women. Neuren and the Rett Syndrome community are hopeful that NNZ-2566 will offer meaningful clinical benefits for patients and families affected by this devastating disorder."

About NNZ-2566

NNZ-2566 is a synthetic analogue of a naturally occurring neuropeptide derived from IGF-1, a growth factor produced by brain cells. In animal models, NNZ-2566 inhibits neuroinflammation and normalises the function of microglia with consequent improvements in molecular, cellular, anatomic and behavioural outcomes. NNZ-2566 is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. The intravenous form of NNZ-2566 is presently in a Phase II clinical trial in patients with moderate to severe traumatic brain injury, which has received Fast Track designation from the US FDA, as well as a Phase II trial in Rett Syndrome. The company intends to implement a Phase II clinical trial in Fragile X Syndrome and an additional Phase II trial with the oral form of NNZ-2566 in patients with concussion or mild TBI.

About Rett Syndrome

Rett Syndrome is a post-natal neurological disorder which occurs almost exclusively in females following apparently normal development for the first six months of life. Typically, between 6 to 18 months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication. Many patients have recurrent seizures. They experience a variety of motor problems including increased muscle tone (spasticity) and abnormal movements. These individuals are never able to provide for their own needs. It is a rare disorder and is believed to be second only to Down Syndrome as a genetically-determined cause of chronic neurological problems that include

severe communication, motor disabilities and epilepsy. Rett Syndrome is caused by mutations on the X chromosome on a gene called MECP2. There are more than 200 different mutations found on the MECP2 gene. Rett Syndrome strikes all racial and ethnic groups and occurs worldwide in 1 of every 10,000 to 23,000 female births.

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.

About Neuren

Neuren Pharmaceuticals Limited (Neuren) is a publicly listed biopharmaceutical company focusing on the development of new therapies for brain injury, neurodevelopmental and neurodegenerative disorders. The novel drugs target chronic conditions such as Rett Syndrome and Fragile-X Syndrome as well as acute neurological injuries. Neuren presently has a clinical-stage molecule, NNZ-2566 in two Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development. Neuren currently has operations in New Zealand and the United States.

For more information, please contact:

Larry Glass, CEO

lglass@neurenpharma.com

Tel: +1 301 941 1830

Dr Richard Treagus, Executive Chairman

rtreagus@neurenpharma.com

Tel: +61 417 520 509