

Neuren (NEU) – ASX Announcement

9 September 2025

Neuren partners with Hope for HIE to support development of NNZ-2591

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) has commenced a formal partnership with Hope for HIE supporting development of NNZ-2591 to treat hypoxic-ischemic encephalopathy (HIE).

Hope for HIE is the global organization connecting families, researchers, clinicians, biotech and more to improve the quality of life for children and families impacted by neonatal and pediatric-acquired Hypoxic Ischemic Encephalopathy, a type of brain injury that has a wide spectrum of outcomes -- anything from minimal impacts to loss of life, and everything in between (<https://hopeforhie.org/>, August 2025).

HIE is a potentially devastating type of brain injury caused when a baby's brain does not receive enough oxygen or blood flow before or shortly after birth. Many thousands of children experience HIE every year. It is one of the leading causes of neonatal death and neurodevelopmental disability worldwide.

Betsy Pilon, Executive Director of Hope for HIE, commented: "Hope for HIE is excited to bring strong expertise in partnering in research to this new partnership, grounded in more than a decade of advocacy, support, resources, and community building across the HIE journey. Our collaboration with Neuren Pharmaceuticals reflects a powerful alignment in values—placing family perspectives and lived experiences at the center of research to meet critical unmet needs. Together, we embody the spirit of hope through therapeutic advancement, pursuing life-changing outcomes for the HIE community worldwide."

HIE can lead to a range of symptoms in surviving children, including developmental delays, cognitive impairment, cerebral palsy, and seizures. Some children develop serious long-term complications that can affect them well into adulthood. Currently, the only approved treatment for HIE is temporary hypothermia (cooling the head or whole body to lower the baby's metabolic rate and give the brain some time to recover from the hypoxic event). Hypothermia provides a modest decrease in mortality and severe neurodevelopmental disability, however even with hypothermia, 40-45% of children who survive HIE have significant neurodevelopmental impairment at 2 years of age. Even among children not diagnosed with neurodevelopmental impairment at 2, many manifest cognitive, behavioural and other functional difficulties as they reach school age and beyond.

Based on its therapeutic properties and results from preclinical research, Neuren aims to demonstrate that NNZ-2591 can provide a differentiated treatment paradigm continuing beyond acute treatment in the neonatal intensive care unit to target both the acute effects and chronic impairments resulting from HIE.

Neuren Chief Science Officer Larry Glass commented: "We are excited to announce this partnership with Hope for HIE. Neuren has a long history of partnerships with patient advocacy organizations which have contributed significantly to our progress in other indications. Hope for HIE's knowledge, experience and commitment will contribute meaningfully to an innovative development program."

About Neuren

Neuren is developing new drug therapies to treat multiple serious neurological disorders that emerge in early childhood and, despite often life-long consequences, have no or limited approved treatment options.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) and Health Canada for the treatment of Rett syndrome. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren's second drug candidate, NNZ-2591, is in development for multiple neurodevelopmental disorders, with positive results achieved in Phase 2 clinical trials in Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome.

Contact:

investorrelations@neurenpharma.com

Larry Glass, CSO: +1 301 758 2987

ASX Listing Rules information

This announcement was authorized to be given to the ASX by the CEO & Managing Director 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.