

Enrolment commences in Neuren's ground-breaking Concussion Phase 2 trial

Melbourne, Australia, 8 September 2014: Neuren Pharmaceuticals (ASX: NEU) announced today that it has received approval from the US Army to commence enrolling subjects in its Phase 2 clinical trial of NNZ-2566 treating concussion. There is currently no approved drug therapy available for acute concussion and Neuren's trial is a world-first commercial sponsored clinical trial of a potential new medicine in this therapeutic area.

The serious health and economic impacts of concussion are increasingly being recognised around the world. Current initiatives are mainly focused on diagnosis, rather than on intervention to address the symptoms of injury. In contrast, Neuren's drug NNZ-2566 has the potential to address cellular and molecular changes in the brain that are known to be caused by concussion. In animal models, NNZ-2566 has been shown to inhibit neuroinflammation, normalize microglial function, restore synaptic signalling and increase IGF-1 expression in the brain.

Neuren's Phase 2 trial is being conducted with the US Army's 82nd Airborne Division at Fort Bragg in North Carolina, as a continuation of the collaboration between Neuren and the US Army on the development of potential therapies for traumatic brain injury. However, the major sporting codes for which concussion has serious health and economic consequences are also a key target market. The profile of the military population for the trial is similar to the profile of athletes in the relevant sports.

Neuren expects that top-line results from the double-blind, placebo-controlled trial will be available in the second half of 2015. Approximately 132 subjects with concussion (also referred to as mild traumatic brain injury) will be enrolled and receive treatment with either NNZ-2566 or placebo for seven days post-injury. Two dose levels of orally administered NNZ-2566 are being tested. A number of measures assessing physical and emotional symptoms and cognitive function will be analysed, together with safety and tolerability measures.

Neuren Executive Chairman Richard Treagus commented; "Given the known properties of NNZ-2566, we are hopeful that this ground-breaking trial can demonstrate the potential for Neuren's drug to help mitigate the serious ramifications of concussions, which are now being recognised in civilian, sporting and military communities around the world."

About concussion and NNZ-2566

Most cases of traumatic brain injury are concussions. A World Health Organization study estimated that 70%- 90% of head injuries are mild, which represents more than 1 million concussions per year in the US alone. However, this estimate of the incidence of concussion may be low given that at least 25% of those affected do not seek or obtain medical care. Concussion is common among young adults participating in contact sports but the incidence is also high in young children, older people and the military.

Recognition of the health impacts of concussions, both in the short term and the long term, and the extent of the serious unmet need for addressing the impacts has been heightened in recent times in the United States and in Australia. President Obama hosted the first White House Healthy Kids & Safe Sports Concussion Summit to advance research on sports-related youth concussions and raise awareness of steps to prevent, identify and respond to concussions in young people. The Summit highlighted commitments to expanding research as well as improving data collection, education and awareness.

The serious impact of concussions in sporting codes, including the US National Football League (NFL) and the Australian Football League, has become a high-profile issue. Well-known football and rugby players in Australia have recently retired following repeated concussions. In the United States, concussions and resulting neurocognitive conditions suffered by NFL players is the subject of pending litigation.

Concussion follows from a bump, blow or jolt to the head and can also occur from a fall or a blow to the body that causes the head to move rapidly back and forth. While these injuries are described as “mild” because concussions are usually not life-threatening, their effects can be serious, persistent and cumulative. Symptoms of concussion are generally grouped into four categories: cognitive function (thinking and remembering), physical (such as headache, dizziness and balance problems), emotional (such as depressed mood, anxiety and anger) and sleep disturbances. In addition to safety and changes in brain injury biomarkers, Neuren’s trial of NNZ-2566 in concussion includes outcome measures designed to assess all of these symptoms.

Concussion disrupts the normal functioning of the brain. The symptoms that may be manifested reflect underlying pathologic changes at the cellular and molecular level. In particular, concussion often results in neuroinflammation, metabolic changes, altered cerebral blood flow and impaired neuronal, axonal and microglial function.

NNZ-2566 is a synthetic analogue of a naturally occurring neurotrophic peptide derived from IGF-1, a growth factor produced by brain cells. IGF-1 signalling has been reported to be affected by concussion. In animal models, NNZ-2566 has been shown to inhibit neuroinflammation, normalize microglial function, restore synaptic signalling and increase IGF-1 expression in the brain. Improvements in cognitive function, affected behaviours and synaptic signalling have also been observed in association with these cellular and molecular effects.

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. Neuren presently has a clinical stage molecule, NNZ-2566 in four Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development. The intravenous form of NNZ-2566 is presently in a Phase 2 clinical trial in moderate to severe traumatic brain injury. The oral form of NNZ-2566 is in Phase 2 trials in Rett Syndrome, Fragile X Syndrome and Concussion. Three programs have received Fast Track designation from the US FDA and the Fragile X Syndrome program has also received Orphan Drug designation.

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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