



Brain Injury Program Update and Pathway to Phase I

- Significant progress made on the pilot traumatic brain injury preclinical study under the Nyrada-UNSW-WRAIR collaboration
- Nyrada to test brain injury drug candidate in preclinical model of stroke, starting in Q1 CY2022
- Phase I study on track to commence in 2H CY2022, evaluating safety and tolerability of Nyrada's drug in two indications, TBI and stroke

Sydney 4 January 2022: Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, today provided an update on the progress of its Brain Injury Program.

Preclinical TBI Efficacy Study Progress

Last year, Nyrada announced a 3-way collaboration with UNSW Sydney and the Walter Reed Army Institute of Research (WRAIR) to evaluate the efficacy of its brain injury drug candidate in two preclinical models of traumatic brain injury (TBI): Controlled Cortical Impact (CCI) and Penetrating Ballistic Brain Injury (PBBI). These models represent two different modes of injury, one as a direct head trauma (CCI) and the other mimicking a bullet or shrapnel wound (PBBI), reflecting serious head injury relevant to active military service members.

In the lead-up to the efficacy study with Nyrada's brain injury drug candidate, a pilot study is being conducted to optimise the design of the efficacy study. Brain samples from the CCI and PBBI models have been collected from WRAIR and are currently undergoing assessment at the Translational Neuroscience Facility of UNSW, utilising their sophisticated MRI technology (T2-weighted and Fractional Anisotropy MRI) to establish the nature and extent of injury. This reflects brain imaging technology used in hospital emergency rooms.

A key focus of this pilot study is to refine the location and extent of injury in each model and select optimal timepoints to assess a therapeutic effect of Nyrada's drug in preventing secondary brain injury. This data will allow the Company to ascertain the number of animals that will be required to provide a meaningful assessment of the therapeutic effect of Nyrada's drug.

Professor Gary Housley, Chair of the Nyrada Scientific Advisory Board, and research head of the UNSW Translational Neuroscience Facility, reports that the imaging of the brain injury models provided to UNSW by the WRAIR Brain Trauma Neuroprotection team are providing key data for powering the Nyrada brain injury rescue drug study.

The Company will provide further updates on the progress of this study as data becomes available.



Testing Nyrada's Brain Injury Drug Candidate in Stroke

Nyrada will evaluate the efficacy of the Company's brain injury drug candidate in a well-established preclinical stroke model in the first quarter of this year. The model is called the Photothrombotic Model of Ischemia, where localised clot formation is achieved in a specific brain region leading to a stroke. This model was previously used by Nyrada to test the efficacy of its first-generation molecule, which showed a promising efficacy signal.

This work is outside of the studies being undertaken as part of Nyrada's collaboration with WRAIR and UNSW. WRAIR's focus remains solely on developing a drug to mitigate the impact of TBI on military service members.

A key advantage of the drug that Nyrada is developing is that it can be administered to stroke and TBI patients in the same manner, by way of intravenous dosing over a 3-day period, which is matched to patient emergency hospital admission.

Nyrada CEO, James Bonnar said, "The development of this model presents an exciting step forward in Nyrada's strategy to evaluate the efficacy of its brain injury drug candidate to reduce the impact of secondary brain injury in patients following a stroke, as well as TBI."

Pathway to Phase I Study

As previously announced, Nyrada expects to commence a Phase I first-in-human study for its Brain Injury Program in the second half of CY2022. The Phase I study will be run in Australia and will evaluate the safety and tolerability of the Company's brain injury drug candidate.

Nyrada CEO, James Bonnar commented: "The Phase I study will support the development of Nyrada's drug in both TBI and stroke indications, significantly expanding the commercial opportunities potentially available to the Company.

"There is still no FDA-approved drug to treat TBI and only limited treatment options for stroke. With 4.1 million TBIs globally in 2020, this remains a large market with a significant unmet clinical need. Through our relationships with the world-class leading research teams at WRAIR and UNSW, Nyrada is in a unique position to develop the first drug to treat both TBI and stroke, with the potential to make a tangible difference in the quality of life of people affected by these injuries," Mr Bonnar added.

Nyrada will provide a further update on the preclinical studies with WRAIR and UNSW, as well as Contract Research Organisation (CRO) selection and study design for the Phase I study in the first half of this year.

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Glossary

T2-weighted MRI	This technique allows for visualisation of the damaged brain tissue based on the intensity. Areas with damage appear hyperintense, whereas healthy brain tissue appears hypointense.
Fractional Anisotropy (FA)	FA is used to measure the integrity of white matter tracts in the brain and provides an assessment of brain connectivity. In an intact brain, the water molecules travel across the length of the axon, where a group of axons form the white matter. In an injured brain, this movement of water molecules is disrupted due to white matter damage. The area where the disruption has occurred can be visualised using this MRI modality.

About the Walter Reed Army Institute of Research (WRAIR)

The Brain Trauma Neuroprotection (BTN) Branch is part of the Center for Military Psychiatry and Neuroscience at WRAIR. The primary mission of the BTN program is to develop ground-breaking solutions to mitigate the effects of TBI at the point of injury to reduce morbidity and mortality. Providing field-based options for diagnostics, preventive strategies, and treatments are critical to Soldiers. Since 1893, the Walter Reed Army Institute of Research (WRAIR) has been a leader in solving the most significant threats to Soldier readiness and lethality such as disease and battle injury. WRAIR's broad research capabilities at its Washington, D.C., area and expeditionary laboratories function in concert to afford Soldiers the best medical protection and support possible before, during, and after deployment by addressing both longstanding and emerging threats. Though WRAIR's research is focused on Soldier health, its products have important civilian applications, saving countless lives around the world.

About the Translational Neuroscience Facility, UNSW

The Translational Neuroscience Facility (TNF) is a core neuroscience research platform in the Faculty of Medicine & Health at UNSW. The TNF broadly supports neuroscience research and advanced translational research training directed towards treatment of neurological disorders.



About Nyrada Inc

Nyrada is a preclinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular and neurological diseases. The Company has two main programs, each targeting market sectors of significant size and considerable unmet clinical need. These are a cholesterol-lowering drug and a drug to treat brain injury, specifically traumatic brain injury and stroke. Nyrada Inc. ARBN 625 401 818 is a company incorporated in the state of Delaware, US, and the liability of its stockholders is limited.

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