



New Drug Offers Potential Oral Treatment for Concussion

- New lead brain injury drug candidate NYR-BI02, shows improved drug-like properties compared to NYR-BI01
- Exploratory study shows NYR-BI02 could be taken orally, the preferred dosing method for concussion patients, as well as administered intravenously, the preferred dosing method for severe TBI and stroke
- No FDA approved drug exists to treat secondary brain injury
- NYR-BI02 selected as the preferred candidate to take forward into a Phase I study

Sydney, 29 March 2022: Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, today announced that its newest brain injury drug candidate, NYR-BI02 has shown excellent oral bioavailability and has been selected to advance into the Company's Phase I first-in-human study. NYR-BI02 is the result of modifications made to NYR-BI01, improving the compound's overall drug-like properties.

There is currently no FDA approved drug to treat secondary brain injury caused by TBI and stroke.

Recent exploratory pharmacokinetic studies undertaken as part of Nyrada's medicinal chemistry program revealed excellent oral bioavailability of NYR-BI02, indicating that Nyrada's drug has the potential to be administered orally to patients who suffer a concussion, where intravenous infusion is not preferred. The convenience of an oral dose form that can be administered in the field immediately after a concussion injury, without having to wait for hospitalisation, has the potential to significantly improve patient recovery outcomes.

Nyrada CEO, James Bonnar said: "The oral bioavailability of NYR-BI02 opens the door for its development as an oral treatment for concussion, which accounts for around 85% of all TBIs. While Nyrada remains focused on the development of our drug for moderate-severe TBI and stroke which would be administered intravenously, pursuing NYR-BI02's development as an oral treatment for concussion is an additional program we may consider, given the significant interest in this area and the positive effect it could have on patient outcomes."

Optimisation of NYR-BI01 has led to an improved candidate NYR-BI02, which has a superior pharmacokinetic profile, meaning it is absorbed, metabolised, and cleared in a manner that supports oral dosing.

Furthermore, we have confirmed that NYR-BI02 readily crosses the blood-brain-barrier, providing assurance that it should reach therapeutic levels in the brain.



Other Updates

Preclinical Stroke Model Study

The Company engaged a contract research organisation (CRO) in China to undertake this study. Unfortunately, the commencement of this study has been delayed slightly as laboratory staff are temporarily unable to access work sites due to COVID-related lockdowns in Shanghai, China. Based on the latest information provided, we expect the study to start shortly and anticipate results will be available in mid Q2 CY2022.

TBI Efficacy Study

NYR-BI02 will be taken forward into the TBI efficacy study which will commence following completion of scale-up manufacturing. A pilot study was undertaken to optimise the design of the efficacy study. Data from this study will be used to determine the number of animals required to show a significant treatment effect. Nyrada continues to work closely with the Walter Reed Army Institute of Research and UNSW Sydney as the program advances.

Phase I Study

As previously announced, the Company anticipates commencing 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 preferred brain injury drug candidate, NYR-BI02.

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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.

www.nyrada.com

Authorised by Mr. John Moore, Non-Executive Chairman, on behalf of the Board.

Investor & Corporate Enquiries:

Laura Vize
Investor Relations Manager
T: 02 9498 3390
E: info@nyrada.com

Company Secretary:

David Franks
T: 02 8072 1400
E: David.Franks@atomicgroup.com.au

Media Enquiries:

Catherine Strong
Citadel-MAGNUS
T: 02 8234 0111
E: cstrong@citadelmagnus.com



Forward-Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections, and assumptions made by Nyrada about circumstances and events that have not yet taken place. Although Nyrada believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that are in some cases beyond the Company’s control (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance, or achievements to differ materially from those expressed or implied by the forward-looking statement.