



Improved Drug Candidate Selected for WRAIR Studies

- New lead drug candidate NYR-BI01 advances to efficacy studies in collaboration with the Walter Reed Army Institute of Research (WRAIR)
- NYR-BI01 showed improved potency, along with excellent Pharmacokinetic (PK) properties and blood-brain barrier penetration
- Drug levels in the brain were significantly higher than those required to deliver a therapeutic effect and NYR-BI01 was well-tolerated throughout the 72-hour study
- WRAIR study to commence in H2 2021 with results expected in Q4 2021

Sydney, 15 June 2021: Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, today announces the selection of a new version of its brain injury candidate (NYR-BI01) to be taken forward into its collaboration studies with WRAIR. NYR-BI01 is a more potent and drug-like version of its predecessor, NYX-1010.

NYR-BI01 showed high potency in a biological assay and impressive drug-like characteristics in a pharmacokinetic (PK) study (see results below in *Figure 1*), intended to determine the level at which it penetrates the brain.

In the PK study, NYR-BI01 was administered to uninjured animals via continuous intravenous (IV) infusion at two doses for 72 hours, 1 and 10 mg/kg/hr, to assess blood concentrations and brain penetration. The study duration aligns with the therapeutic window for preventing secondary brain injury in patients.

James Bonnar, CEO of Nyrada said, “Crossing the blood-brain-barrier at above therapeutic levels with a newly improved and highly potent drug candidate, means our drug can reach the area of the brain damaged by traumatic brain injury. This focus on optimising our drug in preclinical studies enables us to take the best candidate into our studies with WRAIR and eventually into human clinical trials, giving us the best chance of success in Phase I.”

Next steps

The TBI animal models to be used in the planned WRAIR studies are highly specialised and mimic moderate to severe injury in humans. Pilot work is currently being undertaken by WRAIR and UNSW Sydney to determine the baseline injury signal in these models, using multiple MRI techniques, to establish endpoint measurements for therapeutic assessment. MRI is used as a common modality in the clinical setting to assess injury localisation and volume in patients, making the pilot study extremely relevant. Following this pilot work, we anticipate testing of NYR-BI01 in the TBI models at WRAIR will commence in the third quarter of 2021, with the results of the study expected before the end of the year.



Pharmacokinetic Study Results

Figure 1 below shows the concentration of NYR-BI01 in the brain at three separate time points – 6 hours, 24 hours, and 72 hours.

At all three time points for both the 1mg/kg/hour and 10mg/kg/hour doses, drug levels were detected in quantities significantly greater than required to block the intended protein target in brain cells to produce a therapeutic effect. There was a dose-dependent increase (~30x at the 72-hour time point) of the level of drug concentration detected.

Pleasingly, no adverse effects were observed in the animals at either dose level and no significant changes were observed in markers of liver and kidney function or body weight, indicating that the drug is well-tolerated even at the higher dose of 10mg/kg/hour.

In the lead-up to the efficacy study at WRAIR where NYR-BI01 will be tested in an animal model of traumatic brain injury (TBI), this study has provided critical data which will guide the efficacy study design.

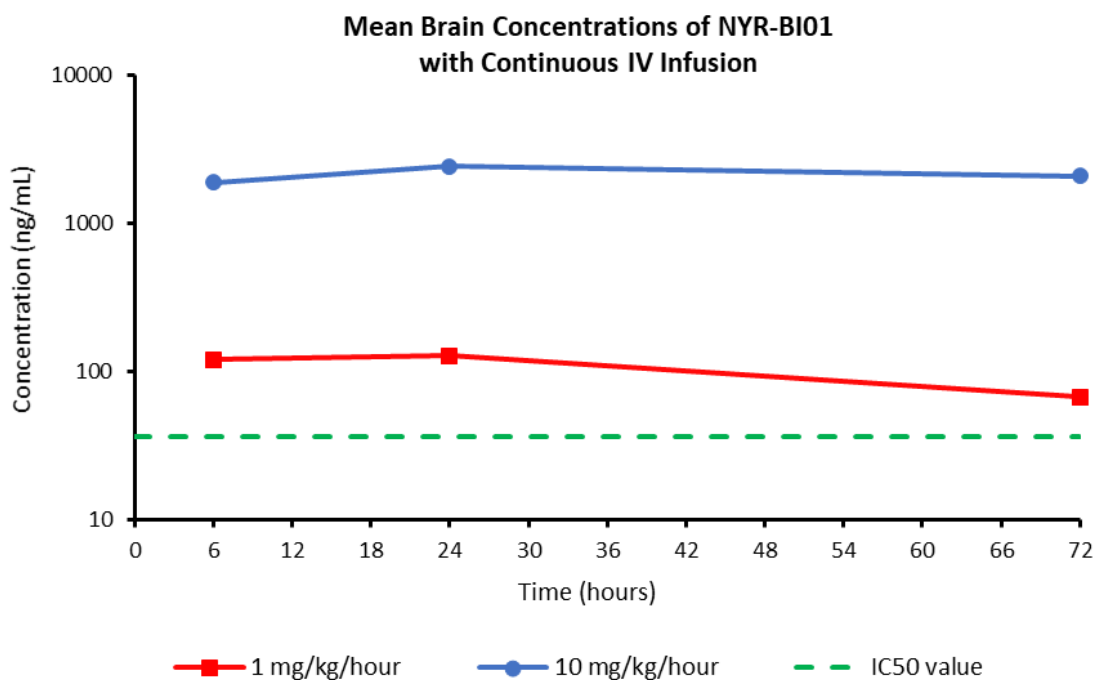


Figure 1 shows the average concentration of NYR-BI01 in the healthy animal brain (n = 4 animals per timepoint) following continuous intravenous infusion at 1 mg/kg/hour (red square) and 10 mg/kg/hour (blue circle) for 72 hours. The dashed green line shows the concentration required for a therapeutic effect (IC₅₀).



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 groundbreaking 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 the 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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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.