



2 May 2025

Sydney, Australia

Phase I Clinical Trial Dosing Update #2

Highlights:

- Nyrada's Phase I clinical trial Safety Review Committee (SRC) has considered cumulative safety and pharmacokinetic data, including from the second dosed cohort.
 - SRC raised no issues, enabling the clinical trial to proceed to the third cohort.
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Nyrada Inc (ASX:NYR), a drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel inhibitors, today provides an update on its Phase I clinical trial.

Clinical Trial

Nyrada has confirmed that the SRC has reviewed cumulative safety and pharmacokinetic data from the first and second cohorts in its clinical trial. No issues were raised, enabling the trial to progress to the third cohort for which recruitment is in progress.

Final Phase I trial readouts are expected in 3QCY2025. Regular updates will be provided throughout the trial.

Lead Drug Candidate NYR-BI03

Nyrada is developing NYR-BI03, a small-molecule, first-in-class drug for neuroprotection and cardioprotection indications.

In February 2024, Nyrada announced [preclinical stroke study results](#) showing that NYR-BI03 achieved a statistically significant neuroprotective effect, rescuing 42% of brain tissue in the penumbra region of treated animals.

In October 2024, Nyrada announced the results of a [preclinical coronary heart disease](#) study, which showed that NYR-BI03 provided an 86% cardioprotective effect following myocardial ischemic-reperfusion injury, a leading cause of tissue damage when blood flow is restored to the heart after injury.

In April 2025, Nyrada announced the results of a [preclinical traumatic brain injury](#) study which showed that NYR-BI03 provided a statistically significant ($p = 0.043$) neuroprotective effect following a penetrating traumatic brain injury. This study was undertaken in collaboration with the [Walter Reed Army Institute of Research](#) and [UNSW Sydney](#).

-ENDS-



Appendix 1 - Key Details of NYR-BI03 Phase I Clinical Trial

Protocol Title	A Phase I, Double-Blind, Placebo-controlled, Randomised, First in Human, Dose Escalation Study to Assess the Safety, Tolerability, and Pharmacokinetics of NYR-BI03 in Healthy Participants, When Administered as a 3-hour Infusion
Primary Endpoints	To evaluate the safety and tolerability of NYR-BI03 in healthy volunteers, when administered as a 3-hour intravenous (IV) infusion
Secondary Endpoints	To determine the blood pharmacokinetics (PK) of an intravenous dose of NYR-BI03 in healthy volunteers when administered as a 3-hour infusion.
Blinding Status	Double-blind, placebo-controlled, randomised
Treatment Method	3-hour intravenous infusion
Number of Trial Subjects	Up to approximately 40 participants will be enrolled (8 participants per cohort for 5 cohorts)
Inclusion Criteria	<ul style="list-style-type: none"> • Informed consent • 18 to 50 years of age • Male or female • Weight 50 to 105 kilograms • Healthy as determined by a medical history
Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy • Allergy or hypersensitivity to formulation or ingredients • Any evidence of organ dysfunction • Liver function or blood clotting tests outside the approved range • Drug and alcohol abuse • Prescription medications taken within 14 days prior to dosing • Psychiatric disorder • Blood donation within 12 weeks prior to dosing • Vaccination or immunisation within 30 days prior to dosing
Trial Location	<p>Scientia Clinical Research The Bright Building Level 5, Corner of Avoca and High Street Randwick NSW 2031 Australia</p>
Principal Investigator	<p>Dr Christopher Argent Scientia Clinical Research</p>
Contract Research Organisation	<p>Southern Star Research Level 1, 1 Merriwa Street Gordon NSW 2072 Australia</p>
Trial Duration	Estimate completion in the quarter ended September 2025



About Nyrada Inc.

Nyrada Inc. is a biotechnology company focused on the discovery and development of innovative small-molecule therapies, specifically targeting Transient Receptor Potential Canonical (TRPC) ion channels. The company's lead candidate, NYR-BI03, has shown efficacy in both neuroprotection and cardioprotection, positioning it for a first-in-human Phase I clinical trial. Nyrada Inc. (ARBN 625 401 818) is incorporated in Delaware, USA, with limited liability for its stockholders.

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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 that could cause the actual results, performance, or achievements to differ materially from those expressed or implied by the forward-looking statement.