



17 March 2025

Sydney, Australia

Nyrada Commences Phase I Clinical Trial Recruitment

Highlights:

- Participant recruitment has now commenced in Nyrada's Phase Ia first-in-human clinical trial.
 - Phase I trial designed to assess safety, tolerability, and pharmacokinetics of lead drug candidate NYR-BI03.
 - First participant dosing expected before end of March 2025.
 - Scientia Clinical Research is the clinical trial site and Southern Star Research is providing Contract Research Organisation services.
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Nyrada Inc (ASX:NYR), a drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel blockers today announces that participant recruitment has commenced for its Phase Ia clinical trial.

Clinical Trial

Nyrada today confirms that participant recruitment has commenced for its Phase Ia clinical trial. The trial is designed to assess the safety, tolerability, and pharmacokinetics of its lead drug candidate NYR-BI03. First participant dosing is expected before then end of March 2025.

The trial will be a double-blind, randomised, placebo-controlled, dose escalating study, comprising five (5) cohorts of eight (8) healthy participants receiving an intravenous dose of either NYR-BI03 or placebo over three hours. There will be six (6) active and two (placebo) participants per cohort.

After each completed cohort, the Safety Review Committee (SRC) will review accumulated safety and pharmacokinetic data. Subsequent dose cohorts may only proceed after favourable review and approval by the SRC.

Further detail on the trial is provided in Appendix 1 and at the US National Institutes of Health (NIH) Clinical Trial Registry. Nyrada has been unable to register details of its trial with the Australia New Zealand Clinical Trials Registry (ANZCTR) as the registry has experienced a cyber incident. Once available, Nyrada will register this trial with ANZCTR.

Final Phase Ia trial readouts are expected in 3QCY2025. Regular updates will be provided throughout the trial. Scientia Clinical Research is the clinical trial site and Southern Star Research is providing Contract Research Organisation services.



Lead Drug Candidate NYR-BI03

Nyrada is developing NYR-BI03, a small molecule, first-in-class neuroprotection and cardio-protection treatment.

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.

-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 and Route	3 hour intravenous infusion
Number of Trial Subjects	Up to approximately 40 participants will be enrolled (8 participants per cohort for 5 cohorts)
Key patient Selection Criteria	<ul style="list-style-type: none"> • Informed consent • 18 years to 50 years of age • Male or female • Weight 50 to 105 kilograms • Healthy as determined by a medical history
Key patient Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy • Allergy or hypersensitivity to formulation ingredients • Any evidence of organ dysfunction • Liver function or blood clotting tests outside 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	Scientia Clinical Research The Bright Building Level 5, Corner of Avoca and High Street Randwick NSW 2031 Australia
Principal Investigator	Dr Christopher Argent Scientia Clinical Research
Contract Research Organisation	Southern Star Research Level 1, 1 Merriwa Street Gordon NSW 2072 Australia
Trial Duration	Estimate completion in 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.