



31 March 2025

Sydney, Australia

## First Cohort Dosed in Nyrada's Phase I Clinical Trial

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### Highlights:

- First cohort of participants dosed in Nyrada's Phase I first-in-human clinical trial.
  - Six participants received NYR-BI03 while two participants received placebo.
  - Phase I trial designed to assess safety, tolerability and pharmacokinetics of NYR-BI03.
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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 completion of dosing in the first cohort of its Phase I human clinical trial.

### Clinical Trial

Nyrada today confirms that the first cohort of participants in its Phase I clinical trial has been dosed and discharged. The trial is designed to assess the safety, tolerability, and pharmacokinetics of lead drug candidate NYR-BI03.

Two sentinel participants were dosed initially, one receiving NYR-BI03 and the other receiving a placebo. Sentinel dosing is a standard safety measure incorporated in first-in-human trials. All cohorts in this Phase I study will commence with sentinel participants.

The remainder of participants in the cohort were dosed following a review of safety data from the sentinels. In total, six participants received NYR-BI03 while an additional two received a placebo in this double-blind, randomised, placebo-controlled, dose-escalation study. The dose of either NYR-BI03 or placebo was administered by infusion over three hours.

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.

Final Phase I 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.

Registration of the trial with the [US National Institutes of Health](#) has also been completed.



### **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.

### **Collaborative TBI Study with WRAIR and UNSW**

Nyrada has been advised that UNSW Sydney has completed the primary analysis for the penetrating TBI study and is currently generating the report.

-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"> <li>• Informed consent</li> <li>• 18 to 50 years of age</li> <li>• Male or female</li> <li>• Weight 50 to 105 kilograms</li> <li>• Healthy as determined by a medical history</li> </ul>
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Allergy or hypersensitivity to formulation or ingredients</li> <li>• Any evidence of organ dysfunction</li> <li>• Liver function or blood clotting tests outside the approved range</li> <li>• Drug and alcohol abuse</li> <li>• Prescription medications taken within 14 days prior to dosing</li> <li>• Psychiatric disorder</li> <li>• Blood donation within 12 weeks prior to dosing</li> <li>• Vaccination or immunisation within 30 days prior to dosing</li> </ul>
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.

[www.nyrada.com](http://www.nyrada.com)

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

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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.