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Sydney, Australia

Nyrada to Commence Phase Ia Clinical Trial

Highlights:

- Nyrada receives Human Research Ethics Committee (HREC) approval to initiate first-in-human Phase Ia clinical trial.
- Trial will evaluate the safety and tolerability of NYR-BI03 in healthy human volunteers.
- Volunteer recruitment to begin shortly, with the first dosing anticipated by the end of March 2025.
- Final Phase Ia trial readout expected in 3QCY2025.

Nyrada Inc (ASX:NYR), a drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel blockers provides today an update on its lead drug candidate clinical development program.

HREC Approval

Nyrada has received approval from the Human Research Ethics Committee (HREC) to initiate its first-in-human Phase Ia clinical trial. The Phase Ia trial will assess the safety, tolerability, and pharmacokinetics of lead drug candidate NYR-BI03 in healthy human volunteers.

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

[Scientia Clinical Research](#) were selected to be the trial site and [Southern Star Research](#) will provide Contract Research Organisation services to support the trial.

Lead Drug Candidate NYR-BI03

Nyrada is developing NYR-BI03, a first-in-class neuroprotection and cardioprotection 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.



Cohort Recruitment and Dosing

Volunteer recruitment will begin shortly with the first cohort dosing anticipated to commence by the end of March 2025. Nyrada's trial site operator, [Scientia Clinical Research](#), will conduct recruitment on Nyrada's behalf based on the HREC approved protocol. Recruitment involves pre-screening and medical assessment prior to inclusion.

Eligible volunteers will be admitted to the clinical unit on Day -1. On Day 1, they will be administered a single intravenous dose of NYR-BI03 or placebo over three hours. Volunteers will be monitored for a further 48 hours for safety assessments and collection of several pharmacokinetic blood samples. They will return to the clinical unit for an end-of-study visit on Day 7 for final safety assessment.

Safety assessments will include monitoring for adverse events, blood tests, physical examination, basic neurological examination, vital signs, and cardiac function.

Human dosing will commence at low drug concentrations and escalate in subsequent cohorts. After each completed cohort, the Safety Review Committee (SRC) will review accumulated safety and pharmacokinetic data.

To accelerate the conduct of the trial, volunteer recruitment will be undertaken in parallel with safety reviews. However, the next scheduled dose cohort may only proceed after favourable review and approval by the SRC. Parallel recruitment will allow subsequent cohort studies to commence promptly following receipt of results from prior cohort.

Nyrada expects final Phase Ia trial readouts in 3QCY2025. Regular updates will be provided throughout.

Commenting on the commencement of Nyrada's Phase Ia clinical trial, Nyrada CEO James Bonnar said: "HREC approval is a very exciting outcome as Nyrada transitions from a pre-clinical to a clinical company.

"The successful completion of this Phase Ia study opens the door to further clinical development across multiple indications. I am very proud of the excellent work and dedication of the dedicated Nyrada team."

WRAIR TBI Study

Nyrada is expecting the results of the joint with WRAIR and UNSW Sydney penetrating TBI study within the coming weeks.

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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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