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Sydney, Australia

NYR-BI03 Phase Ia Clinical Trial Update

Highlights:

- Nyrada is scheduled to submit its regulatory package to Human Research Ethics Committee (HREC) for review before the end of 2024.
 - Updated Phase Ia study design now includes five randomised, placebo-controlled cohorts of eight healthy human volunteers receiving single ascending doses.
 - HREC review to be conducted in January 2025, allowing volunteer recruitment to commence thereafter with dosing expected to be complete in July 2025.
 - Final Phase Ia trial results expected in 3QCY2026.
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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 provides the following update on the Phase Ia clinical trial of its lead drug candidate NYR-BI03.

Lead Drug Candidate NYR-BI03

Nyrada is developing NYR-BI03, a first-in-class neuroprotection treatment for stroke and traumatic brain injury (TBI). In February 2024, the Company 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.

Additionally, 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 early 2QFY2024, Nyrada concluded Good Laboratory Practice (GLP) safety studies of NYR-BI03 providing the Company with the confidence to advance to first-in-human Phase I clinical trial.

Phase Ia Trial

As part of developing its regulatory package for a Phase Ia first-in-healthy human volunteer trial, Nyrada has modified the trial design. This trial design modification has resulted in the delay of the Human Research Ethics Committee (HREC) submission and Phase Ia trial commencement.



The Phase Ia trial will now be a randomised, placebo-controlled study with five (5) cohorts of eight (8) healthy human volunteers receiving single ascending doses.

Nyrada is scheduled to submit its regulatory package for HREC review before the end of December 2024 with HREC review concluded in January 2025. Healthy human volunteer recruitment to commence following approval with dosing expected to be completed by July 2025.

Nyrada will seek to coordinate cohort trials so to report final Phase Ia results in 1QFY2026. Regular updates on Phase Ia study progress will be provided.

[Scientia Clinical Research](#) has been selected as the Phase Ia trial site. [Southern Star Research](#) has been selected as the Contract Research Organisation to support the Phase Ia trial.

Phase Ib Trial and Investigational New Drug Application

Immediately upon completion of its Phase Ia trial, Nyrada intends to commence a Phase Ib trial to assess the safety of NYR-BI03 in multiple ascending doses of longer duration. This is necessary to assess the safety of NYR-BI03 in humans where dosage of up to 72 hours may be required.

Subject to satisfactory completion of Phase I trials, Nyrada's current planning anticipates Phase II trials for stroke and ischemia-reperfusion injury in Australia, and for traumatic brain injury in the US.

In support of this plan, Nyrada will commence preparation of an Investigational New Drug (IND) application to submit to the US Food and Drug Administration (FDA). Upon FDA review and approval, this will enable human studies of NYR-BI03 in the US.

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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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