Sydney, Australia



31 December 2024

# NYR-BI03 Phase Ia Clinical Trial Update 2

# Highlights:

- Nyrada's Phase Ia Clinical Trial regulatory package has been submitted to Human Research Ethics Committee (HREC).
- HREC review expected to be conducted in January 2025, permitting volunteer recruitment to commence thereafter.

**Nyrada Inc (ASX:NYR),** a drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel blockers provides a further update on the Phase Ia clinical trial of its lead drug candidate NYR-BI03.

## Phase la Trial

Nyrada confirms that its Phase Ia first-in-healthy human volunteer clinical trial regulatory package has been submitted for Human Research Ethics Committee (HREC) review. HREC review is expected in January 2025, subject to which, volunteer recruitment will commence.

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

<u>Scientia Clinical Research</u> will be the Phase Ia trial site and <u>Southern Star Research</u> will provide Contract Research Organisation services to support the Phase Ia trial.

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

### Lead Drug Candidate NYR-BI03

Nyrada is developing NYR-BIO3, a first-in-class neuroprotection treatment for stroke and traumatic brain injury (TBI). In February 2024, the Company announced <u>preclinical stroke</u> <u>study results</u> showing that NYR-BIO3 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 <u>preclinical coronary heart</u> <u>disease</u> 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.

-ENDS-



#### 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-BIO3, 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

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.