



16 October 2024

Sydney, Australia

Nyrada Successfully Completes Safety Studies Ahead of Phase I Clinical Trial

Highlights:

- Nyrada successfully completes Good Laboratory Practice safety studies of lead drug candidate NYR-BI03.
- Preclinical studies indicate NYR-BI03 is well tolerated with a favourable safety profile.
- Results from a 14-day rat toxicology study support finalisation of Nyrada's regulatory submission to the Human Ethics Research Committee.
- Nyrada is on track to initiate first-in-human Phase I clinical trial for NYR-BI03 in late 2024.

Nyrada Inc (ASX:NYR), a drug discovery and development company focused on novel small molecule Transient Receptor Potential Canonical (TRPC) ion channel blocking therapies, is pleased to announce the successful completion of the final GLP safety study for its lead candidate NYR-BI03. The Company is now finalising its regulatory submission to the Human Ethics Research Committee (HREC), a critical step towards commencing its first-in-human Phase I clinical trial, anticipated to begin in Q4 2024.

Nyrada CEO James Bonnar commented: "We are thrilled to have completed the GLP studies, which have confirmed a favourable safety profile for NYR-BI03, giving us confidence that it will transition well into human studies.

"The imminent progression of NYR-BI03 into clinical trials is exciting and will mark a significant milestone for the Company, particularly as we now have preclinical evidence supporting its efficacy in both neuroprotection and cardioprotection. This positions us to target three major markets with one therapeutic."

Lead Asset: NYR-BI03

NYR-BI03 is 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.



GLP Safety Studies

Nyrada has now completed a 14-day rat toxicology study for NYR-BI03, in addition to an earlier reported [14-day dog toxicology study](#). These studies, conducted under GLP conditions, administered doses far exceeding the expected therapeutic levels, and showed that NYR-BI03 was well tolerated with no significant safety concerns observed.

This final toxicological assessment represents a major milestone for Nyrada, providing further confidence that the favourable safety profile observed in animals will likely translate to humans. Nyrada has also previously reported that GLP-compliant [in vivo micronucleus](#) and [Ames](#) studies indicated no genotoxic potential.

Based on these strong safety findings, Nyrada is moving forward with its HREC submission, with the pending *in vitro* micronucleus assay considered unnecessary for this submission given the clear negative results from the other genotoxicity tests. The *in vitro* study will be completed and form part of Nyrada's [Investigational New Drug \(IND\) application](#) to the FDA.

GLP Study	Reported
AMES	16 July 2024
hERG	16 July 2024
Rat CNS	06 August 2024
Rat Respiratory	20 August 2024
Dog cardiovascular safety	09 September 2024
14-day Dog Toxicology	27 September 2024
In vivo micronucleus	07 October 2024
14-day Rat Toxicology	16 October 2024

Phase I Clinical Trial

Subject to HREC approval, Nyrada expects to commence a Phase I clinical trial of NYR-BI03 before the end of 2024. This study will assess the safety, tolerability, and pharmacokinetics of NYR-BI03 in healthy volunteers. Pharmacokinetic testing includes evaluating how the drug is absorbed, distributed, metabolised, and excreted in the body.

The Phase I trial, to be conducted in Australia, will provide valuable data applicable to both neuroprotection and cardioprotection programs. The trial is expected to continue until the second half of calendar 2025.

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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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