



6 August 2025

Sydney, Australia

Positive Final Review of Nyrada Phase I Clinical Trial

Highlights:

- Nyrada's Phase I clinical trial Safety Review Committee has reviewed safety and pharmacokinetic data from the sixth and final cohort.
- No dose-limiting safety signals were observed in participants dosed for six hours with Xolatryp™ considered well tolerated.
- Cumulatively, across six cohorts, a total of 48 healthy volunteers received either drug or placebo in this double blind, randomised Phase I trial (40 participants received drug, 8 received placebo).
- Data cleaning is near completion with database lock anticipated by end August 2025. Unblinding and topline results expected to be released in the September 2025 quarter.

Nyrada Inc (ASX:NYR), a clinical stage drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel inhibitors, today announces that its Phase I trial's Safety Review Committee (SRC) has concluded its final meeting to review blinded safety data from its Phase I clinical trial.

Phase I Clinical Trial

The trial's SRC has assessed safety and pharmacokinetic data from the sixth and final cohort of the Phase I clinical trial. Participants in cohort six received Xolatryp™ at the same concentration as cohort five, but with dosing increased from three to six hours, resulting in a double dose compared to cohort five.

Consistent with findings from the previous five cohorts, the SRC confirmed an absence of safety signals, dose-limiting toxicities, or unexpected side effects among the 48 participants dosed in this Phase I study. No serious adverse events (SAEs) were reported, and all observed adverse events (AEs) were classified as either mild or moderate. The SRC is satisfied that Xolatryp remains safe and well tolerated.

Upon unblinding of the study data, it will be determined which participants received Xolatryp or placebo, enabling an assessment of how AEs correspond to treatment allocation.

Pharmacokinetic (PK) assessment of blood samples taken from cohort six participants were also considered by the SRC with confirmation that participants were exposed to twice as much Xolatryp as cohort five participants. A linear PK, consistent clearance, and stable volume of distribution demonstrate predictable dosing within the tested range.



This was the SRC's final meeting to review safety data from this Phase I study.

With final participant assessments now complete, the trial's Contract Research Organisation (CRO), together with the clinical site, is undertaking data cleaning. This is expected to be finalised by the end of August 2025, following which, the database will be locked and unblinded. Once data is unblinded, a Clinical Study Report will be prepared, with an Interim Clinical Study Report projected for completion by the end of the September 2025 quarter. At that time, topline data reporting on primary and secondary endpoints will be made available.

The objectives in this trial were:

- **Primary:** To evaluate the safety and tolerability of Xolatryp in healthy volunteers, when administered as either a 3-hour or 6-hour intravenous (IV) infusion.
- **Secondary:** To determine the blood pharmacokinetics (PK) of an intravenous dose of Xolatryp in healthy volunteers when administered as either a 3-hour or 6-hour infusion.

The Clinical Study Report is expected to be finalised in November ahead of ethics submission for a Phase IIa study.

Phase IIa Clinical Trial

In July 2025, Nyrada announced that it was planning a [Phase IIa clinical to assess the safety and exploratory effectiveness of Xolatryp in patients with acute myocardial infarction](#). The Phase IIa trial will seek to assess safety and explore efficacy in patients with ST-Elevation Myocardial Infarction (STEMI) undergoing Percutaneous Coronary Intervention (PCI).

About Xolatryp™

Nyrada is developing Xolatryp, a first-in-class small-molecule cardioprotection and neuroprotection therapy.

Xolatryp has demonstrated preclinical efficacy as an acute treatment following acute myocardial infarction (AMI), ischemic stroke, and traumatic brain injury (TBI). A Phase IIa clinical trial in patients with AMI is planned for early calendar 2026.

In May 2025, Nyrada announced the results of a follow-up [preclinical coronary heart disease](#) study. This study showed that Xolatryp provided 42% cardioprotection when administered continuously for only 3 hours. In addition to protecting the irreplaceable heart tissue and reducing injury biomarker levels, the incidence of arrhythmias, including ventricular fibrillation and ventricular tachycardia, the leading causes of sudden cardiac death, was significantly reduced.



In April 2025, Nyrada announced the results of a [preclinical traumatic brain injury](#) study, which showed that Xolatryp provided a statistically significant ($p = 0.043$) neuroprotective effect following a penetrating traumatic brain injury. This study was undertaken in collaboration with the [Walter Reed Army Institute of Research](#) and [UNSW Sydney](#).

In October 2024, Nyrada announced the results of a [preclinical coronary heart disease](#) study, which showed that Xolatryp 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. Further [supporting efficacy data](#) were provided through echocardiography assessment that showed significant improvements in heart function and structure following Xolatryp treatment.

In February 2024, Nyrada announced [preclinical stroke study results](#) showing that Xolatryp achieved a statistically significant neuroprotective effect, rescuing 42% of brain tissue in the penumbra region of treated animals.

-ENDS-



About Nyrada Inc.

Nyrada Inc. is a clinical-stage 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, Xolatryp™, has shown efficacy in both cardioprotection and neuroprotection, and has just completed a first-in-human Phase I clinical trial. Nyrada Inc. (ARBN 625 401 818) is incorporated in Delaware, US, with limited liability for its stockholders.

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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.