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Sydney, Australia

Xolatryp™ Achieves Key Clinical Milestone

Highlights:

- Unblinded Phase I results showed trial met its Primary Endpoint, that all Xolatryp doses were safe and well tolerated, with no dose-limiting, or dose-related safety issues.
- Six cohorts included 48 healthy participants (36 received drug, 12 received placebo).
- Human pharmacokinetic profile achieved predicted therapeutic levels and matched preclinical findings.
- Phase IIa clinical trial remains on track to commence in the first quarter of calendar 2026 in patients with acute myocardial infarction.

Nyrada Inc (ASX:NYR), a clinical-stage biotechnology company focused on developing Transient Receptor Potential Canonical (TRPC) ion channel inhibitors to treat a range of medical conditions, today provides an update on its Phase I Clinical Trial following unblinding of clinical data.

Unblinded Results

[As previously disclosed](#), the Safety Review Committee (SRC) for Nyrada's Phase I trial confirmed that final data from cohort 6 demonstrated Xolatryp is safe and well tolerated when administered for up to six hours in healthy participants. Complete unblinded safety and pharmacokinetic data from the Contract Research Organisation (CRO) has been received. This dataset forms an essential component of Nyrada's submission to the Human Research Ethics Committee (HREC) in support of the planned Phase IIa study.

A review of the unblinded data shows that Xolatryp maintains a strong safety profile with no serious adverse events (SAEs) recorded during the trial. Only mild or moderate adverse events (AEs) occurred.

A total of 10 AEs were recorded after dose administration in 8 participants (out of 48). Among those receiving Xolatryp, 14 percent reported AEs, while 25 percent of participants receiving placebo reported AEs. Of the 10 AEs, 5 were considered *not related* to Xolatryp, 1 *unlikely related*, and 4 as *possibly related*. The *unlikely/possibly related* AEs were not dependent on the dose of Xolatryp administered. The most frequently reported AE was headache.

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In addition, the following safety and tolerability parameters were evaluated and did not significantly change from baseline:

- Cardiac safety: ECG and telemetry
- Vital signs
- Laboratory evaluations (haematology, coagulation, chemistry and urinalysis)
- Body weight
- Physical examination
- Infusion site condition (critical for drugs delivered intravenously)

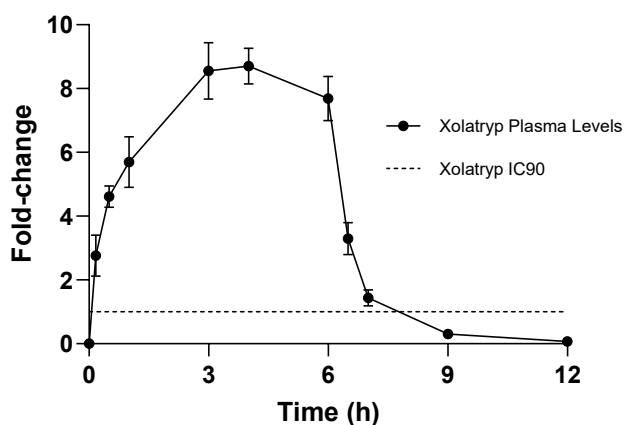
Pharmacokinetic analysis found that Xolatryp showed predictable and linear blood concentrations over time. This is important as it allows for accurate prediction of Xolatryp levels for any dose in the range tested. Additionally, no gender-based differences in Xolatryp blood levels were seen, confirming similar exposure for all participants.

Xolatryp reached blood concentrations considered to be therapeutic (greater than the IC_{90}), within 10 minutes of administration and exceeded this level throughout the six-hour infusion in cohort 6 participants. IC_{90} represents the drug concentration required to inhibit TRPC3/6/7 channels—the intended drug target—with 90 percent effectiveness and is a standard pharmacological metric of drug potency. Rapid drug uptake confirms the suitability for emergency setting administration.

During the infusion, blood concentrations also exceeded the IC_{90} by more than eightfold.

The half-life of Xolatryp, defined as the time needed to decrease blood levels by 50 percent, was consistent with animal data.

Xolatryp Levels in Cohort 6



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Nyrada is continuing to finalise its HREC submission for its Phase IIa clinical trial targeting patients with acute myocardial infarction (AMI) and remains on track to commence patient dosing in the first quarter of calendar 2026.

About Xolatryp™

Xolatryp (formerly known as NYR-BI03) is a small-molecule inhibitor of TRPC3/6/7 channels designed to limit pathological Ca²⁺ entry, protect mitochondrial function, and mitigate ischemia reperfusion injury in AMI and related settings.

[A Phase I clinical trial to assess the safety, tolerability, and pharmacokinetics has been successfully completed](#) and a [Phase IIa clinical trial to assess safety and efficacy](#) is scheduled to commence in the first quarter of calendar 2026 targeting patients with acute myocardial infarction. This trial will seek to assess safety and explore efficacy in patients with AMI undergoing PCI.

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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 (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance, or achievements to differ materially from those expressed or implied by the forward-looking statement.

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