08 January 2026 Sydney, Australia

Nyrada Phase IIa Clinical Trial Approved to Commence

Highlights:

- Nyrada receives Human Research Ethics Committee (HREC) approval to initiate Phase IIa clinical trial.
- Trial will evaluate the safety and preliminary efficacy of Xolatryp® in treating myocardial ischemia reperfusion injury in patients suffering a heart attack.
- First patient dosing expected in March 2026.

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 announces that it has received HREC approval to commence its Phase IIa clinical trial of Xolatryp in myocardial ischemia reperfusion injury.

HREC Approval

Nyrada has received approval from the Human Research Ethics Committee (HREC) to initiate its Phase IIa clinical trial. The trial will evaluate the safety and preliminary efficacy of Xolatryp in treating myocardial ischemia reperfusion injury in patients suffering a heart attack.

The trial is a randomised, double-blind, placebo-controlled, multicentre study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of Xolatryp in male and female patients of non-childbearing potential presenting with a heart attack (or STEMI) undergoing primary percutaneous coronary intervention (PCI) or angioplasty with stenting. Approximately two hundred (200) patients will be dosed for this 1:1 drug to placebo trial.

Although safety is the primary endpoint of this trial, multiple secondary efficacy signals are also being evaluated, including cardiac function, extent of cardiac injury, biomarkers such as troponin I levels, and the incidence of arrhythmias of interest.

HREC approval allows Nyrada to commence establishing trial sites across Australia. Each participating hospital must perform is own Research Governance Office (RGO) review which is mandatory before a site can open. Formal training, led by Nyrada and Accelagen, is then provided to the Investigator Team at each site.

Subsequent, patients presenting to trial site hospitals with a confirmed STEMI (heart attack) will be considered for eligibility to participate in the trial.

Patient recruitment and dosing is expected to commence in March 2026.

Patient Recruitment

Patient recruitment rates are a key determinant of the duration of the trial, and subject to recruitment rates, the trial is expected to conclude within 9 to 18 months of first patient dosing. Approximately 50,000 PCI procedures are conducted annually in Australia.

Up to ten (10) hospitals across Australia will be involved in the trial at any one time. All selected hospitals will have dedicated coronary care units capable of performing PCI.

Recruitment timelines will be closely monitored, and Nyrada's study plan allows for flexible expansion to additional hospitals in Australia or internationally to further strengthen participation. Countries with well-aligned regulatory frameworks, such as New Zealand, Singapore, and Canada, offer potential avenues for broadening the trial's reach. Nyrada also intends to submit an Investigational New Drug (IND) application to the US Food & Drug Administration (FDA), allowing for option to expand the trial into the US.

About Xolatryp®

Xolatryp, previously called NYR-BI03, is a small molecule therapy that inhibits calcium ion influx via TRPC 3/6/7 channels. By limiting pathological calcium entry, it helps protect mitochondrial function and reduces ischemia reperfusion injury associated with acute myocardial infarction (heart attack).

A Phase I clinical trial assessing the safety, tolerability, and pharmacokinetics has been completed, and a Phase IIa clinical trial focusing on safety and preliminary efficacy is scheduled to commence in the first quarter of the 2026 calendar year. This upcoming study will enrol patients suffering from a heart attack who are undergoing PCI (angioplasty with stenting).

-ENDS-

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Appendix 1 - Key Details of Xolatryp® Phase IIa Clinical Trial

(Subject to Change)

Protocol Title (long)	A Randomised, Double-Blind, Placebo-Controlled, Study of Xolatryp® in Patients presenting with STEMI undergoing primary PCI
Protocol Title (short)	A Study of Xolatryp in Patients presenting with STEMI undergoing PCI
Other Title	**P**revention of **R**eperfusion Injury **O**utcomes **T**hrough **E**ffective **C**ardioprotection **T**argeting **M**yocardial **I**nfarction (PROTECT-MI)
Study Description	A Phase IIa, prospective, randomised, double-blind, placebo-controlled, multi-centre study that will evaluate the safety, pharmacokinetics and exploratory efficacy of Xolatryp, in addition to standards of care, in ST-Elevation Myocardial Infarction (STEMI) patients with primary percutaneous coronary intervention (PCI) following 6 hours of continuous infusion.
Primary Objectives	• To evaluate the safety and tolerability of Xolatryp when delivered as an infusion in patients presenting with an acute STEMI undergoing primary PCI • To evaluate the cardiac related safety of Xolatryp when delivered as an infusion in STEMI patients undergoing primary PCI
Further Objectives including	• To determine the cardiac infarct size utilising cardiac MRI in participants with pre-PCI TIMI 0 or 1 flow in patients treated with Xolatryp compared patients treated with placebo • To determine the incidence of arrhythmias of interest in patients treated with Xolatryp compared patients treated with placebo • To determine the blood PK in patients treated with Xolatryp compared patients treated with placebo • To determine the relative difference in serum levels of troponin I in patients treated with Xolatryp compared patients treated with placebo • To compare patient reported outcomes at Day 30 in patients treated with Xolatryp compared patients treated with placebo
Blinding Status	Double-blind, placebo-controlled, randomised, multi-centre.
Treatment Method	3 mg/kg as an intravenous infusion over 6-hours.
Number of Trial Subjects	Approximately 200 patients will be dosed (100 active, 100 placebo)

Key Inclusion Criteria	• Informed consent • Male patients aged 40 to 75 years of age • Female patients aged 55 to 75 years of age, or women less than 55 years that have no possibility of being pregnant • Patient presents with first-time STEMI, scheduled to undergo primary PCI within 6 h of symptom onset • Confirmation of STEMI with ST-elevation at the J-point in two contiguous leads • Hemodynamically stable
Exclusion Criteria	• Prior major cardiac surgery • Known contraindication to CMR • History of clinically significant renal impairment • Body weight < 50 kg or > 120 kg • Pregnant females of childbearing potential or breastfeeding females • Any condition or significant clinical abnormality identified at the time of screening that in the judgment of the Investigator or any sub-Investigator would preclude safe completion of the study
Coordinating Principal Investigator	Professor William Chan MBBS (Hons), FRACP, FCSANZ, PhD
Contract Research Organisation	Accelagen Pty. Ltd. 785 Toorak Road Hawthorn East VIC 3123 Australia

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.

www.nyrada.com

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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.