



30 October 2026

Sydney, Australia

PROTECT-MI Phase IIa Clinical Trial Update #4

Highlights:

- Five (5) sites now activated, and five (5) patients now dosed, up from three [at last update on 16 October 2026](#).
- Recruitment progressing towards the eighth patient, which triggers the first Safety Review Committee (SRC) meeting.
- Liverpool Hospital (NSW) now activated, taking the network to five active sites. Three further sites are expected to be activated by the end of November 2026.
- Additional sites in Australia, New Zealand, Singapore, and Hong Kong under assessment.
- Liverpool Hospital is exploring 24/7 recruitment, which would allow eligible patients presenting overnight and on weekends to be screened and recruited.
- Trial remains on track for final patient dosing in mid-2027, with preliminary results anticipated in 2HCY2027.
- US IND submission for Xolatryp® in STEMI myocardial ischemia reperfusion remains targeted for 1HCY2027.

Nyrada Inc. (ASX:NYR), a clinical-stage biotechnology company developing Transient Receptor Potential Canonical (TRPC) ion channel inhibitors to treat a range of medical conditions, today provides an update on its PROTECT-MI Phase IIa clinical trial.

Trial Sites:

Five sites are currently activated and screening patients. Liverpool Hospital (NSW) has now been activated, joining Nepean (NSW), Sir Charles Gairdner (WA), Northern (VIC) and Royal Perth (WA) hospitals.

Activated sites are recruiting, with all six patients dosed to date recruited at the two longest-activated sites. Nyrada expects the recruitment rate to increase with the recent activation of Liverpool, Royal Perth, and Northern Hospitals.

Nyrada further expects to activate three additional sites by the end of November 2026, expanding the network to eight. These sites are progressing through start-up activities, which includes obtaining internal governance approval, site initiation and staff training, and receipt of Xolatryp.

Nyrada is assessing additional sites in Australia, New Zealand, Singapore, and Hong Kong to expand the trial network and support recruitment.



Patient Recruitment:

Five patients have now been recruited and dosed across two sites, [up from three reported at the last update](#). With three of the five active sites only recently opened and three further sites expected to be activated by the end of November 2026, Nyrada expects recruitment to accelerate over the coming months.

Safety Review Committee:

Nyrada will hold Safety Review Committee (SRC) meetings after 8, 30, 60 and 90 patients have been dosed, and will update the market following each meeting. Recruitment continues throughout and is not paused pending SRC outcomes.

Each SRC meeting is expected to occur at least 14 business days after the last patient in the relevant tranche is dosed, allowing time for PK samples to be shipped for analysis and safety data to be compiled.

Once the eighth patient is dosed (randomised 4 Xolatryp : 4 placebo), Nyrada will have a complete blinded pharmacokinetic (PK) and safety dataset for review at the first SRC meeting.

As PROTECT-MI is a randomised, double-blind, placebo-controlled study, efficacy data will be available once the trial is completed and the data is unblinded.

Timeline to Results:

Nyrada projects that the final patient will be dosed in mid-2027. Following the 30-day follow-up period and approximately 90 days for data cleaning and review, the Company anticipates disclosing preliminary results in 2HCY2027. With five sites now active, additional sites progressing toward activation, and potential screening coverage extension, Nyrada remains confident in this timeline.

Nyrada will continue to update the market on site activations, recruitment milestones, and other material developments as the trial advances.

IND Submission:

Following the positive written feedback from the US Food and Drug Administration (FDA) on its pre-Investigational New Drug (pre-IND) meeting for Xolatryp, announced on [13 October 2026](#), preparation of the US IND package is continuing in parallel with PROTECT-MI recruitment. Nyrada continues to target IND submission in 1HCY2027.

-ENDS-



About Xolatryp®

Xolatryp is a small-molecule inhibitor of TRPC3/6/7 channels designed to limit excessive Ca^{2+} entry related to multiple disease pathologies.

[A Phase I clinical trial to assess the safety, tolerability, and pharmacokinetics has been successfully completed](#) and a [Phase IIa clinical trial](#) has commenced to assess the safety and preliminary efficacy of Xolatryp in reducing cardiac reperfusion injury in patients with ST-Elevation Myocardial Infarction (STEMI) undergoing percutaneous coronary intervention (PCI).

Key Links:

Cardioprotection

- PROTECT-MI website - <https://www.protect-mi.com>
- PROTECT-MI NIH Entry - <https://bit.ly/4cB2fF9>
- Phase IIa factsheet - <https://bit.ly/4bcDIKj>
- FDA IND Feedback - <https://bit.ly/4zyu9dZ>
- Preclinical cardioprotection study 1a - <https://bit.ly/4sigwMZ>
- Preclinical cardioprotection study 1b - <https://bit.ly/4rmOsXn>
- Preclinical cardioprotection study 2 - <https://bit.ly/40jHpUg>

Oncology

- Preclinical cardiomyopathy study - <https://bit.ly/4yR9BgD>
- Preclinical cardiomyopathy pilot study - <https://bit.ly/4xJH3Fi>
- Preclinical anti-tumour study - <https://bit.ly/49rWOa0>

Neuroprotection

- Preclinical traumatic brain injury study - <https://bit.ly/40fhrRT>
- Preclinical stroke study - <https://bit.ly/4sygHmH>

Foundations

- US Patent Grant - <https://bit.ly/4yUqMy>
- Phase I results - <https://bit.ly/3NtOGzH>
- Preclinical mitochondria stabilisation study - <https://bit.ly/4yiZUHa>
- GLP study results - <https://bit.ly/4d8VYkX>
- CSANZ Conference Poster - <https://bit.ly/4A9ROmf>

Corporate

- Latest presentation slides - <https://bit.ly/46FM9Xq>



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 preclinical cardioprotection, neuroprotection, and oncology models and has completed a first-in-human Phase I clinical trial. A Phase IIa clinical trial has commenced to assess the safety and preliminary efficacy of Xolatryp in reducing cardiac reperfusion injury in patients with ST-Elevation Myocardial Infarction (STEMI) undergoing PCI. Nyrada Inc. (ARBN 625 401 818) is incorporated in Delaware, US, with limited liability for its stockholders.

www.nyrada.com

Authorised by Mr. John Moore, Non-Executive Chair on behalf of the Board.

Investor & Media Enquiries:

Dimitri Burshtein

T: 0491 789 391

E: info@nyrada.com

Company Secretary:

David Franks

T: 02 8072 1400

E: David.Franks@automicgroup.com.au

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", "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.