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Sydney, Australia

Nyrada Receives Positive FDA Feedback

Highlights:

- Nyrada has received written feedback from the US Food and Drug Administration (FDA) in response to its pre-Investigational New Drug (pre-IND) meeting request on its Xolatryp® cardioprotection program.
- FDA's response follows a review of Xolatryp's Chemistry, Manufacturing and Controls (CMC) information, nonclinical efficacy, safety, toxicology data, and clinical development briefing package.
- FDA's feedback was supportive of Nyrada's proposed development pathway with no major issues identified.
- Nyrada remains on track to submit its US IND in the first half of the 2027 calendar year.

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, is pleased to announce it has received written responses from the US FDA to its pre-Investigational New Drug (pre-IND) meeting request for Xolatryp®, its lead candidate for reducing reperfusion injury in patients suffering a heart attack.

Background

Nyrada sought the FDA's feedback to support opening an [Investigational New Drug application](#) (IND) so that its PROTECT-MI Phase IIa trial can be conducted in the United States. PROTECT-MI is assessing the safety and preliminary efficacy of Xolatryp in patients with STEMI undergoing primary percutaneous coronary intervention (PCI).

The FDA granted the Type B pre-IND meeting request and provided written responses. This was Nyrada's first interaction with the FDA regarding the Xolatryp program.

FDA Feedback

Nonclinical: The FDA indicated that Nyrada's completed nonclinical safety program appears sufficient in scope to support the Phase IIa study and requested some additional information to be provided in the final IND submission. The FDA also provided guidance on the potential use of existing nonclinical data to support subsequent clinical development, which may reduce the need for additional toxicology studies.

Clinical: The FDA agreed in principle with the patient population and considered the planned safety monitoring measures appropriate. The FDA also indicated that the overall clinical endpoint framework was reasonable for a Phase IIa study.



Cardiac Safety: The FDA confirmed that proceeding with the Phase IIa study before completing a [thorough QT/QTc study](#) is acceptable, based on the available Phase I cardiac safety data and proposed ECG and telemetry monitoring.

CMC: The FDA indicated that the scope of testing for the drug substance and drug product appears appropriate to support IND submission. The FDA will assess the proposed specifications during its IND review and requested that additional stability information be included in the submission.

Regulatory: The FDA acknowledged that ST-Elevated Myocardial Infarction (STEMI) is a serious condition and indicated that a future Fast Track Designation request may be reasonable if the Phase III trial evaluates clinical endpoints reflecting serious aspects of STEMI.

Fast Track Designation can provide more frequent interaction with the FDA and eligibility for rolling review of a marketing application.

Next Steps

Nyrada will address the FDA's recommendations as it prepares its IND submission, which remains targeted for the first half of the 2027 calendar year.

Nyrada's current priority remains recruitment into PROTECT-MI, with preparation of the IND package continuing in parallel.

-ENDS-



About Xolatryp®

Xolatryp is a small-molecule inhibitor of TRPC3/6/7 channels designed to limit excessive Ca²⁺ 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>
- 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

- Phase I results - <https://bit.ly/3Nt0GzH>
- 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. James Bonnar, CEO and Managing Director 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

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