



## Nyrada Completes Preclinical Studies for Cholesterol-Lowering Program

- All required preclinical safety and toxicology studies have been completed, supporting advancement to a first-in-human clinical trial
- Submission to the Human Research Ethics Committee will be made in July for approval to commence Phase I/IIa study
- Phase I/IIa study on track to start early 2H CY2023

**Sydney 26<sup>th</sup> May 2023:** Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, is pleased to announce all of the preclinical Good Laboratory Practice (GLP) studies required by the regulators to evaluate the safety and tolerability of its cholesterol-lowering drug candidate were successfully completed at the end of April. The Company is on track to commence its Phase I/IIa first-in-human study in early 2H CY2023.

### Preclinical Safety and Toxicology Studies Readouts

Preliminary readouts of the safety and toxicology studies are encouraging and pending receipt of the draft GLP study reports, the results pave the way for advancement of the Cholesterol-Lowering Program to Phase I development.

The final draft study report is due in late June, which will enable Nyrada to submit an application to the Human Research Ethics Committee (HREC) in July, for approval to commence the Phase I/IIa study. Subject to ethics approval, the Company aims to finalise the necessary arrangements to dose the first study patient shortly thereafter.

Nyrada is well advanced in the drafting of its submission to HREC, which has been reviewed by the Company's consultant toxicologist and incorporates feedback from the clinical trial site.

### Commenting on the Company achieving this key milestone, Nyrada CEO, James Bonnar said:

"The completion of the preclinical GLP studies and receipt of the draft study reports will allow us to finalise our ethics submission and brings us closer to the initiation of our Phase I/IIa first-in-human study. Nyrada's cholesterol-lowering drug is taking an optimal approach to PCSK9 inhibition that is cost competitive and prioritises patient convenience, compared to the currently available injectable drugs.

"The team has invested significant time behind the scenes to reach this point and I am excited to see the realisation of the value of our drug candidate as we transition to the clinic," Mr Bonnar added.

-ENDS-



## **About Nyrada's Cholesterol-Lowering Clinical Development Program**

### *Phase I/IIa*

We have engaged Scientia Clinical Research (Scientia) to run the Phase I/IIa study. Scientia has world class clinical trial experience and state of the art facilities located in Sydney, NSW, where the study will be run.

The Phase I/IIa study will assess the safety and tolerability of Nyrada's drug candidate, while also providing an early indication of the drug's efficacy in the target patient population.

Phase I/IIa development will be conducted in two stages. The first stage will entail single oral doses being administered to healthy volunteers to determine safety/tolerability, pharmacokinetics and any potential food effect. The second stage will involve dosing participants over a 14-day period to determine safety/tolerability and pharmacokinetics, as well exploring drug efficacy in patients with high cholesterol.

### *Phase IIb Study*

Following completion of the Phase I/IIa study, Nyrada expects to submit an Investigational New Drug (IND) Application to the US Food and Drug Authority, for approval to run a Phase IIb study in high cholesterol patients in Australia and the US. The Phase IIb study will further evaluate the efficacy of Nyrada's Cholesterol-Lowering drug candidate in the target population.



## About Nyrada Inc

Nyrada is a preclinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular and neurological diseases. The Company has two main programs, each targeting market sectors of significant size and considerable unmet clinical need. These are a cholesterol-lowering drug and a drug to treat brain injury, specifically traumatic brain injury and stroke. Nyrada Inc. ARBN 625 401 818 is a company incorporated in the state of Delaware, US, and the liability of its stockholders is limited.

[www.nyrada.com](http://www.nyrada.com)

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

### Investor & Corporate Enquiries:

Laura Vize  
Investor Relations Manager  
T: 02 9498 3390  
E: [info@nyrada.com](mailto:info@nyrada.com)

### Company Secretary:

David Franks  
T: 02 8072 1400  
E: [David.Franks@automicgroup.com.au](mailto:David.Franks@automicgroup.com.au)

### Media Enquiries:

Catherine Strong  
Citadel-MAGNUS  
T: 02 8234 0111  
E: [cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

## 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.