



## Cholesterol-Lowering Program Preclinical Development Update

- Preclinical dose formulation work has been completed
- Toxicology studies have been completed, safety and pharmacology studies to be finalised by the end of April
- Phase I/IIa first-in-human study expected to start early 2H CY2023
- Nyrada appoints Mr. Seth Gordon, a former pivotal member of the Lipitor® marketing team at Pfizer, as Principal Consultant to advise on program strategy and asset development

**Sydney 11<sup>th</sup> April 2023:** Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, today provided an update on its Cholesterol-Lowering Program.

### Phase I/IIa Study Timing

Nyrada previously expected to be in a position to commence a Phase I/IIa study in the first half of the year, however, the formulation work necessary to ensure the Company's cholesterol-lowering drug candidate could be dosed to achieve sufficiently high exposures in preclinical studies required additional time to complete. Consequently, this impacted the progress of a number of the preclinical Good Laboratory Practice (GLP) studies required by the regulators to assess the safety and tolerability of Nyrada's drug candidate prior to commencing a clinical trial. A total of eight studies must be completed. Pleasingly, this work is advancing well, with the last remaining study on track to be completed by the end of April.

Subject to receiving the draft reports for the GLP studies, the last of which is expected to be available in mid-June, we envisage submitting an application to the Human Research Ethics Committee (HREC) in July for approval to commence the Phase I/IIa study. Typically, it can take 6 weeks for a response to be received from HREC. Subject to ethics approval, we plan to finalise the necessary arrangements to dose the first study patient shortly thereafter.

The Phase I/IIa study will assess Nyrada's drug candidate for safety and tolerability, as well as provide an early indication of the drug's efficacy in the target patient population. The inclusion of a small number of high-cholesterol patients in the study positions us well to bring forward the start of a Phase IIb study, a potential time saving of up to 12 months.

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 Nyrada team has been working closely with Scientia as we move to finalise the details of the study protocol.

### **Phase IIb Study**

Following completion of the Phase I/IIa study, Nyrada anticipates submitting 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.

### **Principal Consultant Appointment**

Nyrada also recently appointed Mr. Seth Gordon as Principal Consultant to our Cholesterol-Lowering Program. Seth was a pivotal member of the Lipitor® Marketing team at Pfizer, helping the statin become one of the most successful pharma brands in history. Mr. Gordon will be advising on strategy and asset development, as we look to grow the value of our cholesterol-lowering drug candidate beyond Phase I.

-ENDS-



## 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.*

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