Cholesterol-Lowering Program Pathway to Phase I

- Charles River Laboratories appointed to conduct safety pharmacology and toxicology studies in Nyrada's cholesterol-lowering drug in the US in 1H CY2022
- In addition, Australian world-class clinical research centre to conduct Phase I first-in-human clinical trial, set to commence in 2H CY2022
- Pending ethics committee approval in 2H CY2022, the 14-day Phase I study will recruit approximately 56 healthy volunteers and be conducted in Australia
- The Phase I dose escalation study will evaluate the safety, tolerability, and efficacy of Nyrada's cholesterol-lowering drug candidate
- PCT patent application filed for new generation cholesterol-lowering compounds, broadening protection of Nyrada's PCSK9 inhibitor technology

Sydney, 22 December 2021: Nyrada Inc (ASX: NYR) ("Nyrada" or "the Company") a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases today announced it has appointed internationally recognised Charles River Laboratories, Inc. ("Charles River") to conduct its preclinical studies in the US, ahead of a Phase I cholesterol-lowering trial in Australia. The preclinical studies will be run in the first half of next year, followed by initiation of the Phase I study.

Founded in 1947, Charles River has a long association with enabling the success of its clients in early-stage drug development, supporting the development of more than 80% of the drugs approved by the US Food & Drug Administration in the past three years alone.

The required preclinical studies will be used to evaluate the safety and tolerability of Nyrada's drug in research models. This is a necessary part of the drug development process given Nyrada's candidate has not been tested in humans. Data from these studies will determine the safe starting dose for the Phase I first-in-human study.

Nyrada CEO, Mr. James Bonnar commented, "We are excited to be advancing towards the next phase of our Cholesterol-Lowering Program. Our Phase I clinical trial will be the first time our drug candidate is evaluated in humans, representing a key value inflection point and significant milestone for Nyrada.

"There is considerable industry interest in the development of oral PCSK9 inhibitors and we remain confident that our oral drug candidate, taken as a pill, has the potential to provide an important alternative to expensive and inconvenient injectable PCSK9 inhibitor drugs. The team and I are thrilled to be part of a pioneering approach to cholesterol management," Mr Bonnar added.

The Phase I study will be a first-in-human, double-blind, randomised, dose escalation design evaluating the safety, tolerability, and pharmacokinetics of Nyrada's leading drug candidate in approximately 56 healthy volunteers aged 18 to 50 years. The Company will also evaluate efficacy by measuring changes in LDL or "bad" cholesterol levels in the blood.

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Nyrada's drug candidate will be administered to participants as a once daily oral dose over the 14-day treatment period, to assess safety, tolerability, and efficacy. The trial participants will be split into 7 groups of 8, with each person in groups 1-5 receiving a single dose of Nyrada's drug candidate or placebo, whilst healthy volunteers in groups 6 and 7 will receive a dose of Nyrada's drug candidate or placebo over 14 days. Pathology samples and data will be collected at selected time points over the trial period for all groups.

Pending scale-up manufacturing of the drug and ethics committee approval of the trial protocol, recruitment and dosing of the first participant is expected to commence in 2H CY2022.

In parallel to the preclinical studies to be run at Charles River, Nyrada is also continuing its medicinal chemistry program, which has generated further promising PCSK9 inhibitor analogues to support the Company's Cholesterol-Lowering Program. These new analogues are being evaluated for improved potency and drug-likeness with the potential to generate new intellectual property.

This work has enabled the Company to file a PCT patent application for new generation PCSK9 inhibitor compounds. A PCT patent application makes it possible to seek protection for an invention simultaneously in a large number of countries by filing a single "international" patent application, instead of filing several separate national or regional applications.

This application builds on the patent granted by the US Patent and Trademark Office, as announced on 30 July 2021, and the corresponding European Patent which is in the final stages of examination.

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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.

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Forward-Looking Statements

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