



## Brain Injury Program Update

- *In vitro* safety and toxicology studies commenced 2H CY2022 and are tracking well
- No change to start of Phase I study, expected to commence in 1H CY2023, evaluating safety and tolerability of Nyrada's brain injury drug in two indications, TBI and stroke
- Progression of formulation work necessary for intravenous drug administration causes slight delay to preclinical stroke model study; results expected Q1 CY2023

**Sydney 11 January 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 the progress of its Brain Injury Program.

### Preclinical Studies

#### *Formulation Development*

The formulation development work necessary to ensure Nyrada can deliver an optimal dose form suitable for intravenous administration of our brain injury drug candidate is progressing well. This work is essential for the upcoming *in vivo* safety and toxicology studies, the scheduled Phase I trial and stroke model study.

#### *Safety Toxicology and Pharmacology Studies*

As previously announced, the *in vitro* safety and toxicology studies have started and continue to advance as anticipated, with *in vivo* studies to follow.

The required *in vitro* and *in vivo* preclinical studies will be used to evaluate the safety and tolerability of Nyrada's drug. 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 study.

#### *Stroke Model Study*

The efficacy of Nyrada's brain injury drug candidate is being evaluated in a well-established preclinical stroke model. This model was previously used by Nyrada to test the efficacy of its first-generation molecule, which showed a promising efficacy signal.

The Company previously indicated that this study would be undertaken in the latter part of Q4 CY2022, with results expected early in the new year. However, additional time has been required to progress the formulation development work, resulting in a slight delay to the commencement of the stroke model study. Nyrada now expects the results of the stroke model study to be available during the first quarter of this year.



The stroke study is outside of the work being undertaken as part of Nyrada’s collaboration with the Walter Reed Army Institute of Research (WRAIR) and UNSW Sydney. WRAIR’s focus remains solely on developing a drug to mitigate the impact of TBI on military service members.

**Nyrada CEO, James Bonnar commented:** “The team has been working closely with the US based Contract Research Organisation engaged to undertake the formulation development work for our brain injury drug candidate. This work is critical to the remaining preclinical and Phase I studies and we are very pleased with the results to date.

“This year represents a key turning point for the Company, with both our Brain Injury and Cholesterol-Lowering Drug development programs expected to commence Phase I clinical trials during the first half of 2023. The team and I are excited for what lies ahead,” added Mr Bonnar.

### **Phase I Study**

The Company’s expectations as to the commencement of a Phase I first-in-human study for its Brain Injury Program remain unchanged, with the study to start in the first half of CY2023. The study will evaluate the safety and tolerability of Nyrada’s brain injury drug candidate and will be run in Australia.

-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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