



27 September 2024

Sydney, Australia

## Brain Injury Program GLP Studies Further Update 5

---

### Highlights:

- Dog toxicology study completed providing continuing data to support safety and tolerability of Nyrada's lead Brain Injury drug candidate NYR-BI03.
  - Study was satisfactorily completed under Good Laboratory Practice (GLP) conditions.
  - Nyrada remains on track to commence first in-human Phase I clinical trial for NYR-BI03 in late CY2024.
- 

**Nyrada Inc (ASX:NYR) ("Nyrada or "Company")**, a drug development company specialising in novel small molecule therapeutics provides an update on its Brain Injury program.

Nyrada is pleased to announce the successful completion of a dog toxicology study for its lead candidate, NYR-BI03. This 14-day study, conducted under Good Laboratory Practice (GLP) conditions, assessed NYR-BI03's safety and tolerability profile focusing on general health, body weight, clinical pathology, and pharmacokinetics which measures drug exposure.

This is a key milestone, as dogs being a higher-order species, have physiological systems closely resembling those of humans. This includes their ability to metabolise certain compounds in a manner similar to humans, making them highly relevant in preclinical safety studies. In this study, dogs were dosed at much higher levels than the intended human dose, further reinforcing the safety profile of NYR-BI03.

Standard practice involves conducting GLP studies on two animal species to ensure consistency and reliability of data. In Nyrada's case, both rats and dogs were selected to compare safety profiles across species. A favourable safety profile in both animals strengthens the confidence that these findings will translate to humans. Additionally, testing across multiple species helps identify any species-specific reactions, providing a more comprehensive understanding of the drug's potential effects in humans.

This study marks the sixth successfully completed out of the nine required to advance NYR-BI03 into a first-in-human Phase I trial.



NYR-BI03 is a first-in-class neuroprotection treatment being developed for both stroke and traumatic brain injury (TBI). In February 2024, the Company announced preclinical stroke study [results](#) showing NYR-BI03 achieved a statistically significant neuroprotective effect, rescuing 42% of brain tissue in the penumbra region of treated animals. GLP studies to evaluate the safety and tolerability of NYR-BI03 were initiated in late 1QCY2024 (quarter ending March 2024).

Remaining brain injury program GLP studies will be analysed and reported as they become available.

Subject to satisfactory completion of all GLP studies, Nyrada will submit a Human Research Ethics Application with the expectation of commencing its first in human Phase I clinical trial in late 2QFY2025 (quarter ending December 2024).

GLP Study	Reported
<a href="#">AMES</a>	• 16 July 2024
<a href="#">hERG</a>	• 16 July 2024
<a href="#">Rat CNS</a>	• 06 August 2024
<a href="#">Rat Respiratory</a>	• 20 August 2024
<a href="#">Dog cardiovascular safety</a>	• 09 September 2024
14-day Dog Toxicology	• 27 September 2024
14-day Rat Toxicology	
<i>In vitro</i> micronucleus	
<i>In vivo</i> micronucleus	

-ENDS-

For personal use only



## About Nyrada Inc

Nyrada is a drug discovery and development company specialising in novel small molecule therapies. The Company has two main programs, each targeting market sectors of significant size and considerable unmet clinical need. These are a drug to treat brain injury, specifically traumatic brain injury and stroke, and a cholesterol lowering drug. 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 Chair on behalf of the Board.*

### Investor & Corporate Enquiries:

Dimitri Burshtein

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

Sodali & Co

T: 02 8234 0111

E: [catherine.strong@sodali.com](mailto:catherine.strong@sodali.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.