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Sydney, Australia

Nyrada Brain Injury Drug Candidates Delivered by Preferred Administration Route in Preclinical Pharmacokinetics Study

- Continuous intravenous administration of both lead preclinical drug candidates was maintained at effective therapeutic levels in the brain in a preclinical pharmacokinetics study
- Demonstrates delivery via preferred route for patients suffering from stroke and moderate-severe traumatic brain injury, with desired pharmacokinetic profiles for clinical studies
- Both compounds readily cross the blood-brain-barrier in the uninjured brain of a second animal species, with no observed adverse effects after 6 hours of continuous dosing
- Ongoing study testing intranasal drug delivery, the preferred for route of administration for mild traumatic brain injury and concussion injury, common in sports

Sydney, 15 July 2020: Nyrada Inc (ASX: NYR) reports results from a preclinical pharmacokinetic study of its two lead Brain Injury drug candidates. Both candidates have achieved durable therapeutic levels when administered via continuous intravenous injection, the preferred route for patients suffering from stroke and moderate-severe traumatic brain injury (TBI). Furthermore, no adverse effects were observed in the animals in each arm of the study, indicating that the two drug candidates are safe and well-tolerated at the administered dose.

Stroke and TBI are critical public health problems worldwide with survivors facing severe disability and often requiring long-term care. The Nyrada Brain Injury program aims to develop a treatment for brain injury following stroke and TBI by reducing the build-up of calcium ions in cells, a primary driver of neuronal cell death. Currently, no treatment exists for TBI and the tPA “clot-busting” treatment for stroke is suitable for less than 15% of patients.

Nyrada CEO, James Bonnar commented on the preclinical results: “These latest data provide further evidence that our two potent drug candidates, NYX-242 and NYX-1010, can be given using the preferred route of administration for stroke and moderate-severe TBI patients in the clinical setting. The study also showed that dose levels we anticipate being therapeutic were well-tolerated with no adverse effects observed throughout the 6 hours of dosing. This gives us confidence as we advance both drug candidates into preclinical efficacy studies of stroke and TBI.”

In a previously reported exploratory study (25 May 2020), Nyrada found two of its leading preclinical drug candidates crossed the blood-brain-barrier (BBB) following single bolus intravenous injection. In this follow up study, in a different species, separate cohorts of healthy animals were given a 15 mg/kg dose over 10 mins followed by 5 mg/kg/hr for a total treatment duration of 6 hours.

The figures show the quantity of NYX-242 (a) and NYX-1010 (b) detected in the brain over time and the corresponding IC₅₀ values (dashed line) for block of calcium ion build-up in cells. The IC₅₀ refers to the drug concentration in the brain at which the compounds reduce calcium ion influx through the target pathway by 50% and reflects the anticipated therapeutic threshold.



NYX-242 (a) was detected in the brain at levels corresponding with the therapeutic IC₅₀ and NYX-1010 (b) was detected in the brain at levels far exceeding the IC₅₀ throughout the infusion period. For the planned stroke and TBI efficacy studies, the dose for each drug will be adjusted to exceed the IC₅₀ levels (slightly higher for NYX-242 and much lower for the more potent NYX-1010).

Figure a) NYX-242

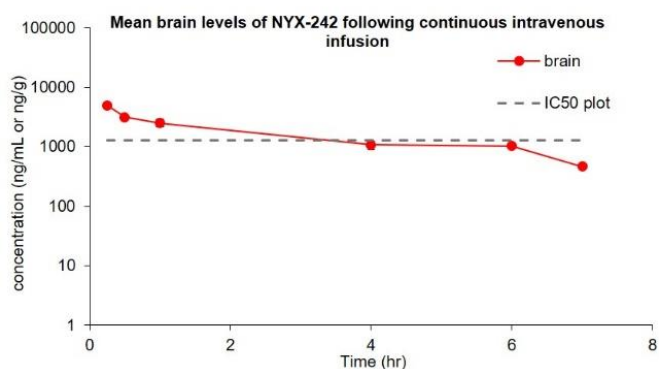
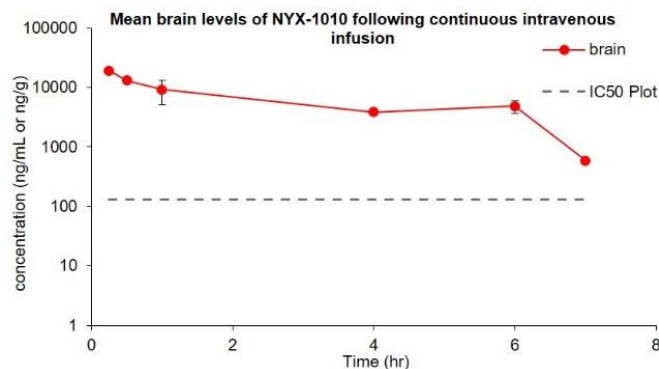


Figure B) NYX-1010



The figures show the average concentration of the two Nyrada compounds NYX-242 (a) and NYX-1010 (b) in the healthy animal brain (n=3 animals per timepoint) following a loading dose (15 mg/kg) over 10 mins and a steady infusion of 5 mg/kg/hr for 5 hours 50 mins. Drug administration was stopped at 6 hours. The dashed lines in both graphs show the corresponding IC₅₀ values of these compounds in blocking calcium ions via the targeted calcium influx pathway.

Why are these results important?

The Nyrada Brain Injury program aims to develop a treatment to prevent secondary brain injury following stroke and TBI, caused by the build-up of calcium ions in neuronal cells to toxic levels resulting in cell death. These results confirm that both Nyrada lead preclinical molecules readily cross into the brain and their levels can be maintained at steady concentrations above the level required to block calcium ion entry and accumulation in cells.

Next Steps

While continuous intravenous infusion is the preferred route of drug delivery for patients suffering from stroke and moderate-severe TBI, Nyrada is also performing a study with intranasal route of delivery, preferred for treatment of mild TBI and concussion injury, common in sports. Nyrada will progress both these drug candidates into preclinical efficacy studies for stroke and TBI.

General

Nyrada has a solid cash position with \$6.1 million in the bank on 31 March 2020. Also, the Company is actively pursuing a variety of non-dilutive funding and collaboration opportunities for the development of its product candidates. The Company also confirms that its operations and supply chains currently remain unaffected by the COVID-19 situation, although the Company is taking precautionary steps to help quarantine its business from any global fallout.



Glossary

Blood-brain-barrier	Blood-brain-barrier (BBB) is a protective barrier between the components of the blood and the cells that form the brain tissue, keeping infection at bay in the healthy brain.
Pharmacokinetics	Term used to describe what the body does to the drug in terms of absorption, distribution, metabolism, and excretion.

About Nyrada Inc

Nyrada is a preclinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular, neurological, and inflammatory/autoimmune 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, USA, and the liability of its stockholders is limited.

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

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Forward Looking Statements

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