

GRANT SECURED TO ADVANCE PRE-CLINICAL STUDIES OF ARG-007

Highlights:

- *Argenica's Chief Scientific Officer, Prof Bruno Meloni and his team at the Perron Institute, have secured a A\$290,000 cash grant to advance pre-clinical research of ARG-007 in preparation for Phase 1 trials.*
- *The animal studies will assist in confirming the optimal effective dose of ARG-007 and confirm its effectiveness when co-administered with clot dissolving drugs.*
- *Results could also further indicate that ARG-007 could potentially continue to offer stroke victims neuroprotection prior to formal diagnosis (imaging) while in-the field, and after clot dissolving drugs are administered in the hospital.*

Perth, Australia; 21 July 2021 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke, is pleased to announce that its Chief Scientific Officer, Prof Bruno Meloni, has secured a grant from MSWA, to advance pre-clinical research of its lead therapeutic candidate ARG-007.

The A\$290,000 cash grant has been awarded to ascertain ARG-007's ideal dose amount for neuroprotective response effectiveness when administered alone, or with clot dissolving tissue plasminogen activator (tPA) drug, in an experimental stroke model. The intellectual property arising from this grant will be assigned to Argenica under the company's Intellectual Property Assignment Agreement for ARG-007.

The project will be led by Prof Bruno Meloni and his team at the Perron Institute for Neurological and Translational Science, and will focus on two core objectives:

1 – CONFIRM OPTIMAL EFFECTIVE ARG-007 DOSE

This work will characterise the neuroprotective dose response efficacy of ARG-007 in different animal stroke models to confirm the optimal effective dose of ARG-007. This will inform Argenica's upcoming Phase 1 clinical trial testing the safety of ARG-007 in healthy human volunteers.

To confirm the most effective dose Prof Meloni and his team will undertake a dose response study with ARG-007 in both a transient and permanent middle cerebral artery occlusion (MCAO) rat stroke model.

Whilst it has previously been confirmed that ARG-007 is neuroprotective after permanent MCAO stroke in the rat at a 300 nmol/kg dose¹, through this study we aim to confirm the most effective dose of ARG-007 in preparation for the Phase 1 trial.

2 – CONFIRM EFFECTIVENESS WHEN USED WITH CLOT DISSOLVING DRUGS

In addition, it is essential that the efficacy of ARG-007 is examined when co-administered with tPA in an animal stroke model, and to confirm its effectiveness when used during thrombolysis treatment. tPA is a clot dissolving drug administered to stroke patients following confirmation of an ischemic stroke and thrombolysis is the treatment regimen to administer tPA.

This study will potentially build on Argenica's positive results announced to the market on 12 July 2021, whereby a preliminary *in vitro* study showed ARG-007 has the potential to continue offering neuroprotection when co-administered tPA.

The findings from this funded project will assist Argenica in confirming the most appropriate escalating dose profile for the upcoming Phase 1 clinical trial. Results from these preclinical studies may also further indicate the likelihood that ARG-007 will continue to offer stroke victims neuroprotection prior to formal diagnosis (imaging) while in-the field, and after clot dissolving drugs are administered in the hospital.

Argenica's CEO, Dr Liz Dallimore said: "Prof Bruno Meloni and his team at the Perron Institute have done a fantastic job in securing this grant. Transitioning from *in vitro* testing to animal studies is a critical part of our pre-clinical program and the importance and quality of the grant application is testament to our highly credentialed scientific team driving ARG-007's development."

Argenica's CSO, Prof Bruno Meloni, said: "I am delighted to be awarded this grant from MSWA. They have been fantastic supporters of neuroscience research in Western Australia, and we are grateful for the ongoing support they have shown our research. Ultimately, the support they are providing for this research project could lead to a new treatment to improve patient outcomes after stroke, not just in Western Australia, but globally."

This announcement has been approved for release by the Board of Argenica.

For more information please contact: info@argenica.com.au

ABOUT ARGENICA

Argenica (ASX: AGN) is developing novel therapeutics to reduce brain tissue death after stroke and improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007 has been successfully demonstrated to improve outcomes in pre-clinical stroke models and is in the process of being verified for its safety and toxicity before commencing Phase 1 clinical trials in humans. The aim is for our therapeutic to be administered by first responders to

protect brain tissue against damage during a stroke with further potential to enhance recovery once a stroke has taken place.

ABOUT ARG-007

Argenica's lead drug candidate, ARG-007, is a cationic arginine-rich peptide which has been in preclinical development by the company's Chief Scientific Officer Prof Bruno Meloni for over 6 years. ARG-007 has shown preclinical evidence of induced neuroprotection in animal models of stroke. Most recently data published in May 2021ⁱ utilising a rodent model of a middle cerebral artery occlusion (MCAO) type stroke showed ARG-007 administration at a dose of 300 nmol/kg resulted in slowing of the infarct core growth and preservation of penumbral tissue. Data gathered in non-human primate animal models of MCAOⁱⁱ showed ARG-007 treatment reduced infarct lesion volume by up to 65.2% and 69.7% at 24 hours and 28 days poststroke, respectively. In this study animals receiving ARG-007 also displayed reduced functional deficits.

ARG-007 has also been shown to be resistant to proteolytic degradation by tissue plasminogen activator (tPA) *in vitro* as described in the company's announcement of 12 July 2021. Argenica believes ARG-007 may have applications beyond stroke with preclinical evidence of efficacy in animal models of traumatic brain injuryⁱⁱⁱ and perinatal hypoxic-ischaemic encephalopathy (HIE)^{iv}, the latter being a leading cause of mortality and morbidity in newborn infants.

ABOUT MSWA

MSWA provides vital support and services to people living with neurological conditions in Western Australia. This includes people living with multiple sclerosis (MS), stroke, Parkinson's disease, Huntington's disease, motor neurone disease, and acquired brain injury, to name a few.

MSWA is a non-government, not-for-profit organisation. The money MSWA raises through fundraising efforts, government grants and other income generating programs goes directly to providing a range of supports and services to people living with neurological conditions.

In addition to direct care services, MSWA also provides funding for vital research projects into neurological conditions.

MSWA's grant recipients can be found at <https://mswa.org.au/news-research/commitment-to-research>

ABOUT THE PERRON INSTITUTE

The Perron Institute for Neurological and Translational Science is Western Australia's longest established medical research institute. The Perron Institute undertakes cutting edge research on a broad spectrum of conditions including stroke, Parkinson's, motor neurone disease, muscular dystrophy, myositis and multiple sclerosis.

One of Perron Institute's special strengths is the connection between the Institute's laboratory research and its 21 specialist clinics. This multidisciplinary approach enables us to translate research outcomes into treatments aimed at providing a better quality of life for millions of people around the world who suffer with devastating neurological conditions.

ⁱ Milani, D., Clark, V. W., Feindel, K. W., Blacker, D. J., Bynevelt, M., Edwards, A. B., Anderton, R. S., Knuckey, N. W., & Meloni, B. P. (2021). **Comparative Assessment of the Proteolytic Stability and Impact of Poly-Arginine Peptides R18 and R18D on Infarct Growth and Penumbra Tissue Preservation Following Middle Cerebral Artery Occlusion in the Sprague Dawley Rat.** *Neurochemical research*, 46(5), 1166–1176.

ⁱⁱ Meloni, B. P., Chen, Y., Harrison, K. A., Nashed, J. Y., Blacker, D. J., South, S. M., Anderton, R. S., Mastaglia, F. L., Winterborn, A., Knuckey, N. W., & Cook, D. J. (2020). **Poly-Arginine Peptide-18 (R18) Reduces Brain Injury and Improves Functional Outcomes in a Nonhuman Primate Stroke Model.** *Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics*, 17(2), 627–634.

ⁱⁱⁱ Chiu, L. S., Anderton, R. S., Clark, V. W., Cross, J. L., Knuckey, N. W., & Meloni, B. P. (2020). **Effect of Polyarginine Peptide R18D Following a Traumatic Brain Injury in Sprague-Dawley Rats.** *Current therapeutic research, clinical and experimental*, 92, 100584

^{iv} Edwards, A. B., Anderton, R. S., Knuckey, N. W., & Meloni, B. P. (2018). **Assessment of therapeutic window for poly-arginine-18D (R18D) in a P7 rat model of perinatal hypoxic-ischaemic encephalopathy.** *Journal of neuroscience research*, 96(11), 1816–1826.