

SIGNIFICANT NON-DILUTIVE FUNDING TO COMPLETE PRECLINICAL HYPOXIC ISCHAEMIC ENCEPHALOPATHY STUDIES

Perth, Australia; 30 March, 2023 - Argenica Therapeutics Limited (ASX: AGN) (“Argenica” or the “Company”), a biotechnology company developing novel neuroprotective therapeutics, is pleased to announce the receipt of non-dilutive cash funding from the Stan Perron Charitable Foundation (SPCF) to the Perron Institute for Neurological and Translational Sciences (The Perron Institute) to progress preclinical studies into the efficacy of ARG-007 in neonatal Hypoxic Ischaemic Encephalopathy (HIE). This non-dilutive grant funding will be used to complete the preclinical animal studies required to progress ARG-007 into clinical trials in newborn infants suffering HIE.

Previous studies assessing the efficacy of ARG-007 in both a preterm (announced 3 November 2021) and term (announced 29 September 2022) rat model of neonatal HIE showed a significant reduction in the amount of brain cell death following administration of ARG-007 in HIE. In the term model, a 300 nmol/kg dose of ARG-007 reduced neuronal cell death by 86% compared with saline controls 24 hours post administration.

To move ARG-007 into human clinical trials in newborn infants preclinical efficacy studies in rats and larger animal models, plus juvenile toxicology studies in rats, are required to be completed. The total cost of all preclinical animal efficacy and toxicology studies is approximately AUD3.6million. The grant will cover the costs of the preclinical animal efficacy studies in rats, and the preclinical efficacy studies in a large *term* animal model of HIE and a large *preterm* animal model of HIE. Argenica will cover the costs of the juvenile toxicology study which is in the order of AUD1.1m. The efficacy studies will be led by Argenica’s Neonatal Scientific & Regulatory Advisor, and postdoctoral research fellow at the Perron Institute, Dr Adam Edwards, in collaboration with neonatologists Dr Jane Pillow, Director of the University of Western Australia Preclinical Intensive Care Research Unit (PICRU) and Dr Kasper Kyng, Clinical Associate Professor in the Neonatal Intensive Care Unit at Aarhus University Hospital, Denmark. Once completed, these studies will aid Argenica to progress ARG-007 into clinical trials in infants suffering HIE.

Dr Liz Dallimore, Argenica’s Managing Director, said “The support of the Stan Perron Charitable Foundation for this important research led by Dr Edwards is extremely generous. The Foundation is an incredible organisation allowing Western Australian research into the health and wellbeing of children flourish. We are optimistic about the therapeutic potential of ARG-007 in HIE and look forward to working with Dr Edwards and his collaborators to progress these critical studies.”

Whilst Argenica will not directly receive these funds, and therefore there will be no impact on the Company's balance sheet, ownership of all newly generated intellectual property related to ARG-007 created through the project activities and commercialisation rights of ARG-007 as a treatment for HIE will remain solely with Argenica. Argenica will now work with the Perron Institute and the SPCF to finalise the grant agreement. Further details on the program of work and the terms and conditions of the grant will be provided once agreed.

In parallel to the preclinical program of work to move ARG-007 into human clinical trials, Argenica is working with global contract research organisation Labcorp Drug Development's (Labcorp) paediatric regulatory team to develop a regulatory and clinical trial strategy for ARG-007 in HIE in newborns. Labcorp has extensive experience in planning and running global paediatric clinical trials, as well as obtaining regulatory investigational new drug applications, and orphan drug designation from the Food and Drug Administration for therapies targeting rare paediatric therapies.

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 other types of brain injury and neurodegenerative diseases to improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007, has been successfully demonstrated to improve outcomes in pre-clinical stroke models, traumatic brain injury (TBI) and hypoxic ischaemic encephalopathy (HIE). The Company has recently completed a Phase 1 clinical trial in healthy human volunteers to assess the safety and tolerability of a single dose of ARG-007. Argenica is now progressing towards a Phase 2 clinical trial in ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions, including in TBI, HIE and Alzheimer's Disease.

ABOUT HIE

HIE, a **rare paediatric condition**, is a type of brain injury sustained by newborns whereby the brain doesn't receive enough oxygen or blood flow for a period of time. There are a number of causes of HIE, including placental rupture, umbilical cord problems, or other factors. The condition may develop during pregnancy, labour and delivery, or during the postnatal period. Whilst some babies effected by HIE will only sustain mild effects, others will have severe and permanent disability including cerebral palsy, developmental delays, severe disability, or cognitive impairment. Currently the only treatment for HIE in newborn term infants is brain cooling, or hypothermia, however studies show that whilst this treatment may be well tolerated and safe for term babies, in 31-55% of babies the treatment has been shown to be ineffective at providing improved neurological outcomes¹. This treatment is not appropriate for preterm babies, and there are currently no therapies available for preterm babies who suffer HIE.

¹ Shankaran S. Therapeutic hypothermia for neonatal encephalopathy. *Curr Treat Options Neurol.* 2012;14(6):608–19