ARGENICA PARTNERS WITH LINEAR CLINICAL RESEARCH FOR PHASE 1 CLINICAL TRIAL

Perth, Australia; 30 September 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 it has engaged world leading clinical research institution, Linear Clinical Research (Linear) to initiate the preliminary work required for its Phase 1 clinical trial.

Linear has a purpose built state-of-the-art, clinical trial facility operating out of QEII Medical Centre in Perth, Western Australia, with a 29,000 strong healthy volunteer database from which to recruit for Argenica's Phase 1 trial. Since 2010, Linear has conducted over 170 studies across 19 therapeutic areas and has extensive experience in Phase 1 trials, including adaptive healthy volunteer and patient protocol designs.

Following execution of the agreement between the two parties, Linear will begin preliminary study start-up activities for the Phase 1 trial, including protocol familiarisation, clinical site management setup, preparation of ethics submission, booking clinical beds for the length of the trial, and establishing the clinical study monitoring.

Argenica's Phase 1 clinical trial will be conducted in healthy volunteers to assess the safety, tolerability, and pharmacokinetics of single ascending doses of ARG-007. The trial is anticipated to be run as a double-blind, randomised, placebo-controlled, sequential-groups study. The trial has been designed to include a total of 32 participants enrolled in 4 groups of 8 people. Each participant will either receive a dose of ARG-007 or a placebo on Day 1, with safety pathology samples and data collected at multiple points over the following 8 days.

For a 3D fly-through of Linear's facility where the Argenica trial will take place, head to the following URL:

https://www.veriscian.com/show/f4qbz21ydcb/linear-clinical-research-limited

The trial will provide Argenica with critical data on the safety and tolerability of ARG-007. The purpose of the Phase 1 trial is to determine if ARG-007 is safe and well tolerated when administered in healthy human subjects. Data collected from the trial will also provide the required foundation to progress into a Phase 2 trial, where, assuming ARG-007 is safe and well tolerated in human subjects in its Phase 1 trial, ARG-007 will be administered to stroke patients.

The Company aims to release further details on its Phase 1 clinical trial, including an estimated timing roadmap, primary endpoints, information on the patient cohorts and dosing amounts as these details are confirmed with Linear.

Argenica's Chief Executive Officer, Dr Liz Dallimore said: "We are excited to partner with Linear who have fantastic credentials in conducting successful clinical trials for organisations across the globe. They can offer us a full-service solution incorporating trial design, patient recruitment and final data analysis. We will now move forward with the Preliminary Work required to set up the trial, working towards the project delivery timelines to ensure the quality execution of our Phase 1 trial."

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 2021[i] 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 MCAO[ii] 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 injury[iii] and perinatal hypoxic-ischaemic encephalopathy (HIE)[iv], the latter being a leading cause of mortality and morbidity in newborn infants.

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[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 Penumbral 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.