SUCCESSFUL COMPLETION OF PHASE 1 CLINICAL TRIAL DOSING AND COMMENCEMENT OF PHASE 2 TRIAL PLANNING

Highlights:

- *Argenica successfully completes dosing in pivotal Phase 1 clinical trial, with ARG-007 shown to be safe and well tolerated at all doses administered to healthy participants.*
- *The fourth dosed cohort, which received the highest dose of ARG-007, showed no adverse events related to the administration of the drug.*
- *Argenica has commenced planning for a Phase 2 trial to assess the safety, tolerability, and efficacy of ARG-007 in ischaemic stroke patients.*
- *The Company continues to progress preclinical studies in other indications, including hypoxic ischaemic encephalopathy and traumatic brain injury.*

Perth, Australia; 21 December 2022 – Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other types of brain injury, is pleased to announce the **successful completion** of dosing in its Phase 1 clinical trial, with the fourth and final cohort dosing and follow up now complete.

Throughout the trial all four doses of ARG-007 were well tolerated with **no serious adverse events** observed. In the fourth cohort, following an extensive review of data from the participants, including blood pressure, vital signs, neurological examinations, haematology, and adverse events, the safety review committee (SRC) determined that there were no clinically relevant abnormal results due to the administration of ARG-007.

Of the eight participants dosed (six receiving ARG-007 and two receiving a placebo), **no serious adverse events** were observed following dosing. Further information on non-serious adverse events has now been provided to Argenica and the SRC by the trial Clinical Research Organisation, Linear Clinical Research (Linear). In this final cohort, participants received the highest dose of ARG-007. **None of the participants experienced any non-serious adverse events** related to the administration of ARG-007.

Argenica CEO and Managing Director, Dr Liz Dallimore said: “The completion of dosing in Argenica’s Phase 1 clinical trial is a pivotal milestone for the Company. We have successfully shown that ARG-007 is safe and well tolerated in healthy humans. This is incredibly exciting for the Company as it now paves the way for Argenica to test ARG-007 not only in stroke patients but also patients with other neurological conditions where a single dose of ARG-007 has already shown efficacy in preclinical studies. This includes conditions such as hypoxic ischaemic encephalopathy, cardiac arrest, and severe traumatic brain injury.

For further information on the Phase 1 trial design, please refer to the Phase 1 Trial Summary announced on 8 September, 2022.

Linear will now compile all trial data and prepare the interim analysis report to be completed in March 2023 prior to providing Argenica the final Clinical Study Report which will likely be received in May 2023. The Clinical Study Report will provide the data required for Argenica to submit the Phase 2 ethics application.

PLANNING FOR PHASE 2 CLINICAL TRIAL IN STROKE PATIENTS

Argenica has already commenced planning for its Phase 2 clinical trial in ischaemic stroke patients. The Phase 2 trial is expected to be a Blinded Assessment, Randomized, Placebo-Controlled, Parallel Group Study to Determine the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of a Single Dose of ARG-007 in Acute Ischemic Stroke Patients. The trial is expected to be conducted at multiple hospitals across Australia and will test the primary outcomes of safety and tolerability in patients that have suffered an acute ischaemic stroke caused by a clot in a large vessel in the brain. The Phase 2 trial is expected to also gather efficacy data via imaging and functional assessments post treatment.

The Company is currently in discussions with a number of global Clinical Research Organisations (CROs) with experience in conducting Phase 2 trials in acute emergency settings in Australia to determine the most appropriate CRO to undertake this pivotal trial. Following selection of a CRO, Argenica will work closely with them to finalise the trial protocol and investigational brochure required for submission to the Human Research Ethics Committee (HREC) seeking approval to commence the trial.

The ethics submission for this Phase 2 trial will be through the National Mutual Acceptance program which allows for a single scientific and ethical review by a Certified Reviewing HREC for approval of a multi-site clinical trial. This means Argenica will only be required to submit its ethics application to one HREC at one hospital to gain approval to conduct the trial across multiple Australian hospitals, thereby speeding up the time to approval. Argenica aims to submit its ethics application for approval to commence this Phase 2 trial in Q3 calendar year 2023 following receipt of the Phase 1 Clinical Study Report and finalisation of the Phase 2 protocol.

PROGRESSING MULTIPLE INDICATIONS OUTSIDE OF STROKE

Whilst Argenica commences planning for its Phase 2 trial in ischaemic stroke patients, the Company continues to undertake a number of pre-clinical studies in indications outside of stroke. This includes preclinical work in hypoxic ischaemic encephalopathy, traumatic brain injury and other neurological conditions in which ARG-007 may have a therapeutic benefit. The Company looks forward to updating its shareholders over the course of 2023 as to the outcomes of these preclinical studies for ARG-007 in these other indications.

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 other neurological conditions. It has verified the safety and tolerability of ARG-007 in a Phase 1 clinical trial in healthy human volunteers. The aim is for our therapeutic to be administered in emergency departments, clinical settings and by first responders to protect brain tissue against damage during a stroke and other neurological conditions with further potential to enhance recovery in patients effected.