PHASE 2 STROKE CLINICAL TRIAL UPDATE

Highlights:

- ***A total of 74 patients*** *have been dosed in Argenica's Phase 2 clinical trial in acute ischaemic stroke (AIS) patients, representing* ***80%*** *of total patients to be dosed in the trial.*

- *As per the study protocol, the independent Data Safety Monitoring Board (DSMB) will meet to review safety data of patients 47 to 69 (representing the 75% of patient's dosed milestone). This DSMB meeting is anticipated* ***to occur at the end of January****.*

- *Given the trial is recruiting 92 patients in total,* ***there are 18 patients left to be dosed*** *in the Phase 2 trial. Following dosing of the last patient, Argenica expects topline data, incorporating the 90 day post dosing functional assessments, to be received four and a half months after the last patient is dosed.*

- *Recruitment of patients into the trial is on track to complete dosing of all 92 patients* ***before the end of Q2 calendar year 2025****.*

- *Argenica's Investigational New Drug application is anticipated to be ready for submission in the coming weeks.*

Perth, Australia; 10 DECEMBER 2024 - 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 provide an update on the progress of the Company's Phase 2 clinical trial in acute ischaemic stroke (AIS) patients.

PATIENT RECRUITMENT

Since the first patient was dosed at the end of March 2024 (see ASX announcement dated 28 March 2024), a total of **74 patients,** out of a total recruitment target of 92 patients, have now been recruited and dosed in the trial. This represents 80% of the trial patient cohort. . Dosing in the Phase 2 trial will be completed when a total of 92 patients have been dosed, meaning **the trial requires 18 more patients to be dosed.**

To date, feedback from the trial sites has been very positive, with no issues reported with regards to patient consent or the ability to recruit and dose patients. Based on anticipated recruitment rates at each site, recruitment of patients into the trial is on track to complete dosing of all 92 patients before the recruitment target of the end of **Q2 calendar year 2025**.

DATA SAFETY MONITORING BOARD

As part of the Phase 2 trial, Argenica has established an independent DSMB comprising a number of independent neurologists and a biostatistician, who will be responsible for reviewing the safety data as the trial progresses. The DSMB will also be supported by an unblinded project manager and statistician.

The purpose of the DSMB is to monitor the rates of adverse events (AEs), endpoints, and study progress in the Phase 2 trial. In addition, the DSMB provides recommendations regarding the continuation, modification, or termination of the study to Argenica and will practice due diligence to ensure, given all available information, that subsequent subjects are not placed at any undue risk.

The primary purpose of the data review meeting is to allow the DSMB to review and discuss the safety data outputs in order to make recommendations on whether any variations to the study protocol may be required and to confirm that the study can continue. The outcomes of these meetings will be made available to the market.

To date, the DSMB has met three times to review patient safety data, being after the first 5 patients dosed, the subsequent 18 patients, and at 46 patients dosed. There have been no serious adverse events possibly related to administration of the drug product in the first 46 patients dosed and assessed by the DSMB (ASX announcements dated 29 April, 6 September, and 1 November 2024). The DSMB will conduct one more meeting at the end of January 2025 to assess patient data from patients 47 to 69 and make a recommendation as to whether the study may continue as per the study protocol for the remainder of the trial. Trial enrolment will not be halted during the planned DSMB review of the safety data. This will be the last DSMB to be held prior to completion of patient dosing.

INVESTIGATIONAL NEW DRUG APPLICATION

Argenica is currently preparing an Investigational New Drug (IND) application to submit to the US Food and Drug Administration (FDA). By opening an IND application with the FDA, sponsors of clinical trials receive authorisation to administer an investigational drug or biological product to humans. Any future later phase clinical trials of ARG-007 to be undertaken at sites in the US requires this authorisation from the FDA. The submission and approval of Argenica's IND has no bearing on the ability of the Company to complete its current Phase 2 clinical trial.

Preparing an IND application is a lengthy process and requires extensive data to be included on a drug's preclinical and nonclinical efficacy, safety and tolerability, as well as the drugs chemistry, manufacturing and development controls. Argenica is working with its US based regulatory consultant to prepare the IND application for submission to the FDA, with the majority of the submission already complete. The Company anticipates the application will be ready for submission to the FDA in the coming weeks following a quality review process.

Dr Liz Dallimore, **Managing Director of Argenica**, stated "*The pace of recruitment in our Phase 2 clinical trial has exceeded our expectations and we are grateful for the dedication and hard work of the teams at the trial sites. As we approach the final stages of dosing in this trial, we are working tirelessly to set Argenica up for later stage clinical trials to test the efficacy of ARG-007 in stroke, including ongoing dialogue with potential partners. The next few months are extremely exciting for the Company, and we look forward to continuing to work closely with the trial sites to complete patient dosing.*"

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 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 undertaking a Phase 2 clinical trial in acute ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions.