POSITIVE DSMB SAFETY OUTCOME & PHASE 2 TRIAL PROGRESS UPDATE

Highlights:

- *The Data Safety Monitoring Board (DSMB) has reviewed the safety data of the first 23 patients dosed in Argenica's Phase 2 clinical trial and* ***recommends the study continue*** *with no modifications required to the Study Protocol.*

- ***No serious adverse events or adverse events*** *related to the dosing of patients were reported to the independent DSMB.*

- *All 10 hospitals sites across Australia are now* ***activated to administer ARG-007 to acute ischaemic stroke patients.***

- *To date there have been* ***43 patients dosed*** *in Argenica's Phase 2 stroke trial, which means dosing is 47% complete, with 6 of the 10 activated hospitals having dosed patients. The next DSMB meeting will be held following the dosing of a total of 46 patients.*

- *Based on the success of recruitment and dosing to date, it is anticipated dosing of all 92 patients will now be* ***completed by the end of Q2 calendar year 2025.***

Perth, Australia; 6 September 2024 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other neurological conditions, is pleased to announce that the independent Data Safety Monitoring Board (DSMB) has recommended that the Phase 2 clinical trial of ARG-007 in acute ischemic stroke patients continues with no modifications to the study protocol.

Undertaking a review by an independent DSMB complies with Good Clinical Practice (GCP). The purpose of the DSMB is to monitor the rates of adverse events (AEs), endpoints, and study performance in the Phase 2 clinical trial of ARG-007. In addition, the DSMB can provide 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 DSMB is an independent multidisciplinary committee consisting of a Chairperson, two physicians and a biostatistician with relevant clinical trial experience.

The DSMB will continue to make recommendations as to whether the study may continue as per the study protocol throughout the trial. Subsequent patient safety reviews by the DSMB are also scheduled at least every six months, subject to recruitment rates with the next meeting to be held post dosing of the next 23 patients (which will be a total of 46 patients dosed in the trial).

Of the first 23 patients dosed, the average age of participants is 68.1 years, with 10 men and 13 women dosed. The trial is stratifying patients into two groups, patients that receive tissue plasminogen activator (tPA), which dissolves blood clots, and those that don't, to allow Argenica to determine whether there is any impact of ARG-007 on tPA, and vice versa, in a clinical setting. Therefore, the split been these two groups is even, with 11 participants receiving tPA and 12 participants not receiving tPA.

PHASE 2 TRIAL RECRUITMENT UPDATE

All 10 hospital sites are now activated and able to recruit and dose patients in Argenica's Phase 2 trial of ARG-007 in AIS patients. As sites have become familiar with the trial protocol there has been an increase in the recruitment rate and dosing of patients in the trial with a total of **43 patients** having been dosed.

Given the trial has already recruited 47% of the patients required to be dosed (43 out of 92), it is anticipated the next DSMB meeting will be held in Q4 calendar year 2024 following the dosing of 46 patients. Argenica now anticipates dosing of all 92 patients in the trial will be completed by the end of Q2 calendar year 2025.

Dr Liz Dallimore, **Managing Director of Argenica**, stated "*It is pleasing to see there were no dosing related adverse events reported to the DSMB, and that the trial can continue unchanged. We are equally pleased by the successful recruitment and dosing rates being achieved as these are currently exceeding our initial expectations. We are grateful to the independent DSMB for completing this important review of safety data of the first 23 patients in our Phase 2 clinical trial and we look forward to working with the DSMB throughout the trial as they provide their recommendations.*"

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