POSITIVE DSMB SAFETY OUTCOME & PHASE 2 TRIAL PROGRESS UPDATE

Highlights:

- *The Data Safety Monitoring Board (DSMB) has reviewed the safety data of the first 46 patients dosed in Argenica's Phase 2 clinical trial, which represents 50% dosing completion, and* ***recommends the study continue*** *with no modifications required to the Study Protocol.*

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

- *To date there have been* ***58 patients dosed*** *in Argenica's Phase 2 stroke trial, which means dosing is* ***63% complete****, with 7 of the 10 activated hospitals having dosed patients.*

- *The next DSMB meeting to review safety data will be held following the dosing of a total of 69 patients.*

Perth, Australia; 1 November 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 serious and non-serious adverse events, 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 an independent Chairperson neurologist, two additional independent neurologists and a biostatistician with relevant clinical trial experience.

Importantly there were no serious adverse events in the 46 patients dosed to date. One patient suffered two non-serious adverse events that have been reported as possibly related to the administration of ARG-007. This patient suffered bradycardia (slowed heartbeat) and hypotension (low blood pressure) more than 8 hours after dosing in the trial, with the patient recovering from both adverse events quickly. As the trial is double blinded, it is not known if this patient received placebo or ARG-007 and accordingly under the study protocol, such events must be reported.

Of the 46 patients reviewed under the DSMB, the average age of participants is 71.3 years, with 17 men and 29 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 between these two groups is stratified, with 18 participants receiving tPA and 28 participants not receiving tPA.

The next DSMB meeting to review safety data and make a recommendation as to whether the study may continue as per the study protocol will be held post dosing of the next 23 patients (i.e. total of 69 patients dosed in the trial).

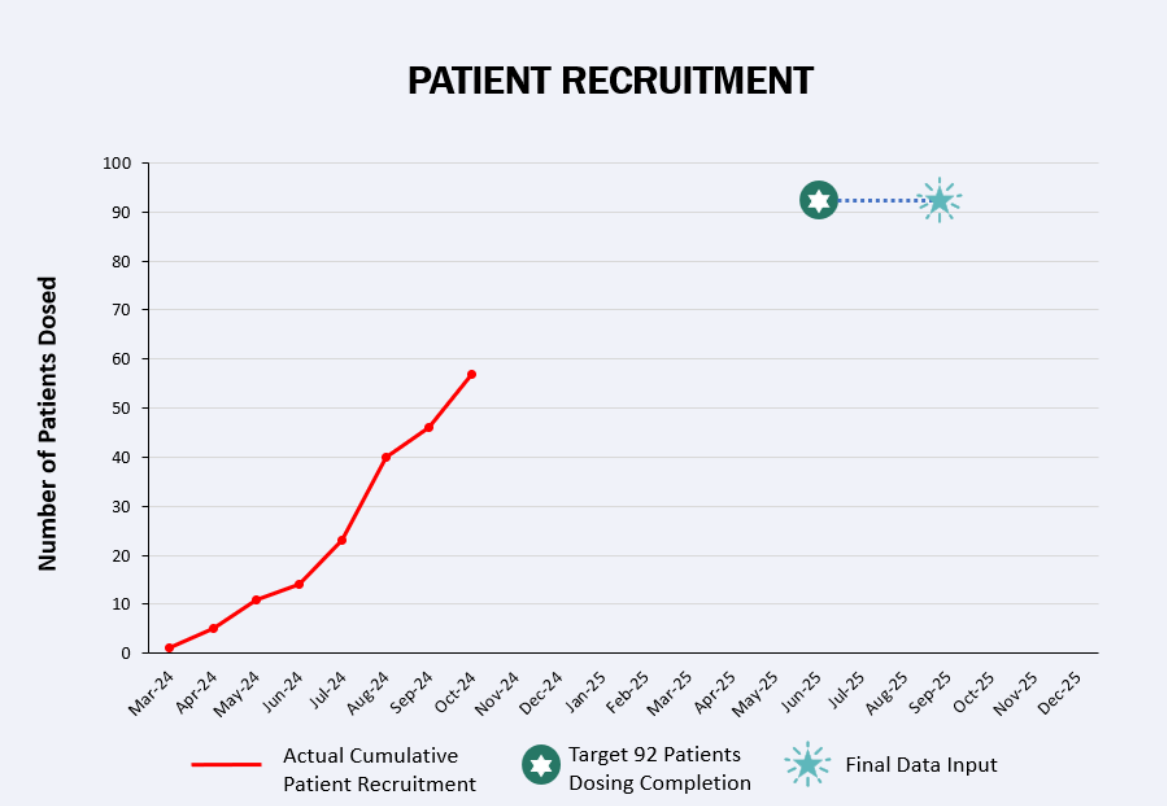
PHASE 2 TRIAL RECRUITMENT UPDATE

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. Of the 10 sites activated, 7 sites have now dosed patients, with a total of **58 patients** of 92 (63%) having been dosed.

Argenica notes that three sites have yet to dose patients, however given the enthusiasm of the sites to be included in the trial, the Company is confident that the sites will be recruiting patients in the near term.

Argenica anticipates dosing of all 92 patients will be completed by the end of Q2 CY25. This timing accounts for periods of expected low recruitment over December and January. Further, Argencia's CRO has confirmed topline data will be provided within weeks of the final 90 day follow up of last patient dosed.

An overview of trial recruitment to date is provided below:



Dr Liz Dallimore, **Managing Director of Argenica**, stated "*We are delighted to have passed the halfway milestone of dosing in our Phase 2 trial and achieved currently 63% recruitment. This is a significant milestone for the Company and with a green light from the DSMB to continue the trial unchanged, demonstrates we are delivering on our stated objectives. We thank the investigators, and all personnel involved for their dedication and commitment to the study.*"

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.