

POSITIVE FINAL DSMB SAFETY OUTCOME & PHASE 2 TRIAL PROGRESS UPDATE

Highlights:

- *The Data Safety Monitoring Board (DSMB) has reviewed the safety data of the first 76 patients dosed in Argenica's Phase 2 clinical trial, which represents a review of 83% of patients in the study, and **recommends the study continue** with no modifications required to the Study Protocol.*
- *This is the last DSMB to be held for Argenica's Phase 2 trial in acute ischaemic stroke (AIS) patients.*
- *To date there have been **79 patients dosed** in Argenica's Phase 2 stroke trial, which means dosing is **86% complete**, with 8 of the 10 activated hospitals having dosed patients.*
- *Whilst December and January have had slow recruitment, as expected, Argenica anticipates dosing to be completed in **early Q2 CY2025**.*

Perth, Australia; 30 January 2025 - 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 AIS 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.

The data pack that the DSMB reviewed included information on one serious adverse event (SAE) that was deemed by the hospital site's principal investigator to be possibly related to the study drug administration. The investigator also noted in their assessment that other concomitant medication the participant was on could have also caused the SAE and therefore

deemed only possibly related. 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. Based on a review of this patient’s data, along with the remaining patient data, the DSMB deemed the trial was safe and could continue unchanged and no further DSMB review is required

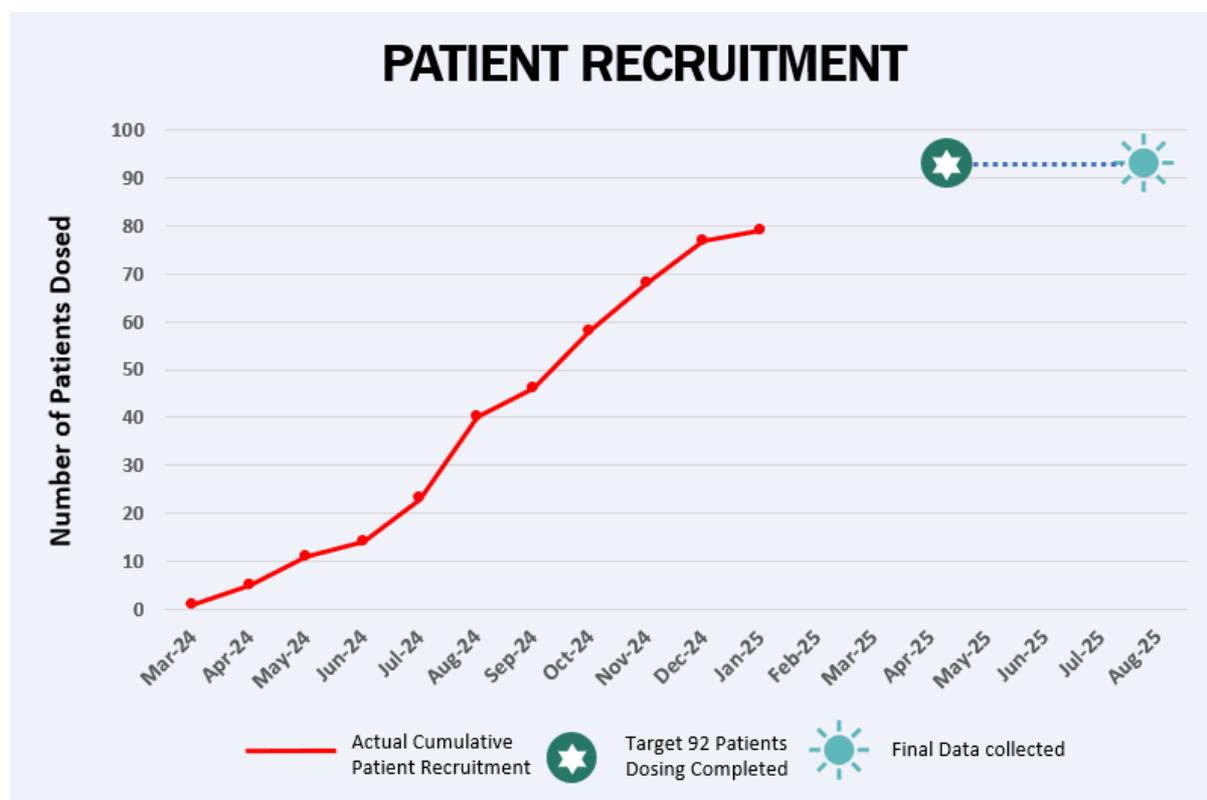
Of the 76 patients reviewed under the DSMB, the average age of participants is 72.0 years, with 32 men and 37 women dosed. The trial is stratifying patients into two groups, patients that receive tissue plasminogen activator (tPA), which dissolves blood clots, and those that don’t, to allow Argenica to determine whether there is any impact of ARG-007 on tPA, and vice versa, in a clinical setting. The split between these two groups is stratified, with 28 participants receiving tPA and 41 participants not receiving tPA.

Given the patient dosing is near completion, this is the final DSMB to be held for Argenica’s Phase 2 trial of AIS patients. The Company will provide an update once patient dosing is complete.

PHASE 2 TRIAL RECRUITMENT UPDATE

Of the 10 sites activated, 8 sites have now dosed patients, with a total of **79 patients** of 92 (86%) having been dosed.

Given the strong rate of recruitment overall, Argenica anticipates dosing of all 92 patients will be completed in early Q2 CY25. Argenica’s Clinical Research Organisation partner 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 *“This final DSMB represents a significant milestone for the Company as we near completion of patient dosing in our Phase 2 trial of acute ischaemic stroke patients. Argenica would like to thank the independent members of the DSMB for their dedication and commitment to this study. DSMBs play an integral role in ensuring the safety of trial participants, and without their professionalism and expertise, our trial could not have progress. We look forward to continuing to work with our trial sites to complete patient dosing over the coming months.”*

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.