DSMB CONFIRMS SAFETY OF FIRST PATIENTS DOSED IN PHASE 2 STROKE TRIAL

Highlights:

- *The Data Safety Monitoring Board (DSMB) has reviewed the safety data of the first five 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.*

- *Four of the ten hospitals sites are* ***activated to administer ARG-007 to acute ischaemic stroke patients****, being Royal Melbourne Hospital, Princess Alexandra Hospital, John Hunter Hospital and Liverpool Hospital. Royal Adelaide Hospital and Royal Brisbane Women's and Children's Hospital have undergone site initiation visits and will be activated imminently.*

Perth, Australia; 29 April 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 will 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 meetings to

be held post dosing of 23 patients, 46 patients, 69 patients, and at the completion of dosing of all 92 patients.

Four of the ten hospitals participating in the trial are now activated and able to dose patients, being The Royal Melbourne Hospital, Princess Alexandra Hospital, John Hunter Hospital and Liverpool Hospital. Royal Adelaide Hospital and Royal Brisbane Women's and Childrens have undergone site initiation visits and will be activated imminently. The remaining four hospitals will be activated over the next three months following governance approval.

Dr Liz Dallimore, **Managing Director of Argenica**, stated "*We are grateful to the independent DSMB for completing this important first review of safety data in our Phase 2 clinical trial. 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 ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions, including in TBI, HIE and Alzheimer's Disease.