FIRST PATIENT DOSED IN PHASE 2 STROKE TRIAL OF ARG-007

Highlights:

- *The **first patient** in Argenica's Phase 2 clinical trial in acute ischaemic stroke patients has been **successfully dosed.***

- *The patient, who presented to the Royal Melbourne Hospital emergency department, was **enrolled into the trial** following a confirmed diagnosis of an acute ischaemic stoke caused by a large vessel occlusion (LVO) and being eligible for mechanical thrombectomy.*

- *Three of the ten hospitals sites are **activated to begin patient dosing**, being Royal Melbourne Hospital, Princess Alexandra Hospital and John Hunter Hospital. Another three hospitals will be activated in the next month, and the remaining four hospitals will be activated over the next three months following governance approval.*

- *The first assessment of patient safety will be conducted by the Data Safety Monitoring Board following dosing of the first five patients.*

Perth, Australia; 28 March 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 first acute ischaemic stroke (AIS) patient has been dosed in its Phase 2 clinical trial of ARG-007.

The patient presented to the Royal Melbourne Hospital emergency department with a suspected AIS. Following confirmation of a large vessel occlusion (LVO) suitable for a mechanical thrombectomy procedure, and meeting other eligibility criteria for inclusion in the Phase 2 trial, the patient was dosed with an intravenous infusion. Given this is a blinded clinical trial, none of the trial staff, nor Argenica staff, know whether the patient received ARG-007 or the placebo.

Three of the ten hospitals participating in the trial are now activated and ready to dose patients, being Royal Melbourne Hospital, Princess Alexandra Hospital, and John Hunter Hospital. Another three hospitals will be activated in the coming weeks, being Liverpool Hospital, Royal Adelaide Hospital, and Royal Brisbane Women's and Children's Hospital. The

remaining four hospitals will be activated over the next three months following governance approval.

Following dosing of the first five patients, a review of patient safety will be conducted by the clinical trial Data Safety Monitoring Board (DSMB). Additional patient safety reviews will be conducted by the DSMB following dosing of 23 patients, 46 patients, 69 patients, and at the completion of dosing of 92 patients.

Dr Liz Dallimore, **Managing Director of Argenica**, stated "*We are absolutely delighted to have officially commenced our Phase 2 clinical trial by dosing our first stroke patient*. *We will be carefully monitoring the recruitment of patients in this trial, and report progress as we go. We have engaged an amazing clinical trial team in hospital stroke units across Australia and are looking forward to continuing to work with them throughout the trial.*"

PHASE 2 STROKE CLINICAL TRIAL OVERVIEW

The Phase 2 trial is a Multicentre, Double-Blinded, Randomized, Placebo-Controlled, Parallel-Group, Single-Dose Study to Determine the Safety, Preliminary Efficacy, and Pharmacokinetics of ARG-007 in Acute Ischemic Stroke Patients (SEANCON).

The trial is designed to test how safe ARG-007 is in acute ischaemic stroke (AIS) patients, with safety being a significant regulatory hurdle in neurology drug development. Proving ARG-007 is safe in AIS patients will pave the way for Argenica to progress to a pivotal Phase 3 trial and further engage with global pharmaceutical companies.

Furthermore, the trial is designed to generate preliminary data on the ability of ARG-007 to reduce brain tissue death following stroke and mechanical removal of brain clot (thrombectomy). Proving the neuroprotective ability of ARG-007 will be a significant de-risking milestone for the Company and opportunity to place Argenica at the forefront of neuroprotective clinical validation.

The trial will enrol only patients with a diagnosed large vessel occlusion (LVO) stroke that are eligible for endovascular thrombectomy (mechanical removal of a clot in the brain). By narrowing the patient selection to both a specific range of LVO strokes and those receiving endovascular thrombectomy, it will ensure the trial has improved control for end point evaluation to power a successful outcome. LVO strokes account for close to 40% of all acute ischaemic strokes, however, are responsible for 60% of post-stroke dependency and 90% of mortalities after stroke, and therefore are considered the most devastating type of stroke[1].

The trial will be conducted in up to 10 hospitals across Australia that have dedicated stroke care units capable of performing endovascular thrombectomy. As patients enter the

[1] Malhotra K, Gornbein J, Saver JL. Ischemic Strokes Due to Large-Vessel Occlusions Contribute Disproportionately to Stroke-Related Dependence and Death: A Review. Front Neurol. 2017 Nov 30;8:651.

emergency department with a suspected AIS, they will be assessed for eligibility to participate in the trial by the principal investigator (PI) neurologist at each trial site.

Following treatment, patients will be assessed for key safety outcomes as well as infarct volume and functional outcomes via a number of standard assessments.

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.