PATIENT DOSING MILESTONE ACHIEVED IN PHASE 2 STROKE TRIAL

Highlights:

- ***Argenica successfully doses <u>five patients</u>*** *in its acute ischaemic stroke Phase 2 clinical trial, representing the first cohort of patients to be reviewed by the Data Safety Monitoring Board (DSMB), highlighting a promising early recruitment response to date.*

- *The patients, who presented to both the Royal Melbourne Hospital and Princess Alexandra Hospital emergency departments, were* ***enrolled into the trial*** *following meeting the inclusion criteria: a confirmed diagnosis of an acute ischaemic stoke caused by a large vessel occlusion (LVO) and were eligible for mechanical thrombectomy.*

- ***No serious adverse events or adverse events*** *related to the dosing of patients have been reported, with a comprehensive review of the safety data by the independent DSMB to follow.*

- *Three of the ten hospitals sites are* ***activated to begin patient dosing****, being Royal Melbourne Hospital, Princess Alexandra Hospital and John Hunter Hospital. Liverpool Hospital and Royal Adelaide Hospital have undergone site initiation visits and will be activated imminently, followed closely by Royal Brisbane Women's and Children's Hospital.*

Perth, Australia; 10 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 first cohort of acute ischaemic stroke (AIS) patients have been dosed in its Phase 2 clinical trial of ARG-007.

Following dosing, patients are monitored closely for any serious adverse events and adverse events. No serious adverse events or adverse events related to patient dosing have been reported to date. In accordance with the study protocol the data (including safety data) from the first five patients will now be reviewed by the independent Data Safety Monitoring Board (DSMB). The DSMB will make a recommendation as to whether the study may continue as per the study protocol. Subsequent patient safety reviews by the DSMB are also scheduled

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

The patients in this first cohort presented to the Royal Melbourne Hospital and Princess Alexandra emergency departments 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 patients were dosed with an intravenous infusion of ARG-007. Given this is a blinded clinical trial, none of the trial staff, nor Argenica staff, know which of the patients received ARG-007 or the placebo.

Three of the ten hospitals participating in the trial are activated and able to dose patients, being Royal Melbourne Hospital, Princess Alexandra Hospital, and John Hunter Hospital. Both Liverpool Hospital Royal Adelaide Hospital have undergone site initiation visits and will be activated imminently. The Royal Brisbane Women's and Children's Hospital will undergo a site initiation visit tomorrow and be activated shortly thereafter. 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 extremely appreciative of the commitment the hospitals have shown in actively managing, recruiting, and dosing patients. To achieve dosing of the first safety cohort after less than two weeks is a testament to the dedication of the clinical trial teams working in the emergency departments of our trial sites. We look forward to providing ongoing updates on the recruitment and DSMB outcomes as the trial progresses.*"

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 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.

[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.