PHASE 2 STROKE CLINICAL TRIAL UPDATE

Highlights:

- ***Eight of the ten hospitals*** *participating in Argenica's Phase 2 clinical trial have now been activated, with the remaining two hospitals to be activated by the end of July 2024.*

- *Since the first patient was dosed at the end of March 2024, a total of* ***20 patients*** *have been recruited into the trial and dosed at five of the eight activated sites.*

- *Having all hospitals activated from the beginning of August will allow* ***greater recruitment of patients*** *presenting to hospital emergency departments with diagnosed acute ischaemic strokes, and which meet the trial's inclusion criteria.*

- *As per the study protocol, the independent Data Safety Monitoring Board (DSMB) will meet to review safety data once 23 patients have been dosed. This is anticipated to occur in the coming weeks.*

- *Recruitment of patients into the trial is on track to complete dosing of all 92 patients before the recruitment target of the end of calendar year 2025.*

Perth, Australia; 24 JULY 2024 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke, is pleased to provide an update on the progress of the Company's Phase 2 clinical trial in acute ischaemic stroke (AIS) patients.

SITE ACTIVATION

Eight of the ten hospitals participating in the Phase 2 trial have now been activated, with the remaining two hospitals, being Monash Health and Gold Coast Hospital, expected to be activated by the end of July. Of the eight activated sites, two only completed activation at the end of June, being Fiona Stanley Hospital and Royal Brisbane & Women's, and Sir Charles Gairdner was only activated this week.

For the remaining two hospitals, Monash Health and Gold Coast Hospital, site initiation visits have now been completed and activation of those sites will be completed by the end of July.

Having all hospitals activated from the beginning of August 2024 will mean more access to eligible patients presenting to hospital emergency departments with diagnosed acute ischaemic strokes, and which meet the trial's inclusion criteria.

PATIENT RECRUITMENT

Patient recruitment is progressing as anticipated, with five of the eight activated sites having recruited and dosed patients. Since the first patient was dosed at the end of March 2024 (see ASX announcement dated 28 March, 2024), a total of **20 patients** have now been recruited and dosed in the trial. The last two sites activated in late June, and the site activated this week, are yet to recruit patients, which is to be expected given it takes time for each site to become familiar with the study protocol and commence the patient screening process.

To date, feedback from the trial sites has been very positive, with no issues reported with regards to patient consent or the ability to recruit and dose patients. Based on anticipated recruitment rates at each site, recruitment of patients into the trial is on track to complete dosing of all 92 patients before the recruitment target of the end of calendar year 2025.

DATA SAFETY MONITORING BOARD

As part of the Phase 2 trial, Argenica has established an independent Data Safety Monitoring Board (DSMB) comprising a number of independent neurologists and a biostatistician, who will be responsible for reviewing the safety data as the trial progresses. The DSMB will also be supported by an unblinded project manager and statistician.

The purpose of the DSMB is to monitor the rates of adverse events (AEs), endpoints, and study progress in the Phase 2 trial. 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.

During the trial, there will be five planned data review meetings with the DSMB. The primary purpose of the data review meeting is to allow the DSMB to review and discuss the safety data outputs in order to make recommendations on whether any variations to the study protocol may be required and to confirm that the study can continue. The outcomes of these meetings will be made available to the market.

The first data review meeting occurred in April after the first 5 subjects were dosed in the trial with no drug related adverse events reported (ASX announcement dated 29 April, 2024). 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 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. Trial enrolment will not be halted during each planned DSMB review of the safety data. The next DSMB is anticipated to be held in Q3 CY2024 following recruitment of the first 23 patients.

Dr Liz Dallimore, **Managing Director of Argenica**, stated "*We are delighted with the progress of the Phase 2 trial to date. We are very encouraged by the fact that recruitment is progressing well and the investigators at the hospitals that have recruited patients have all been extremely positive about the study protocol. We look forward to having all trial sites activated and recruiting patients in the coming weeks, which will give us greater clarity on patient recruitment rates and when we can expect to complete the study. We will continue to provide trial updates as recruitment of patients 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 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.

[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.

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.