ARGENICA RECEIVES ETHICS APPROVAL TO COMMENCE PHASE 1 TRIAL

Highlights:

- *Argenica receives ethics approval to commence its pivotal Phase 1 clinical trial of ARG-007 in healthy participants.*
- *The process to recruit healthy volunteers into the trial will now commence through Linear Clinical Research, who will be running the trial. Dosing of the first cohort of volunteers is expected to commence in October.*
- *Up to 32 subjects will be dosed across 4 dose escalating cohorts to assess the safety, tolerability and pharmacokinetics of ascending doses of ARG-007 in healthy volunteers.*

Perth, Australia; 7 September 2022 - 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 announce the Company's ethics application to Bellberry's Human Research Ethics Committee (HREC) to commence a Phase 1 healthy participant study of ARG-007 **has been approved**.

The trial will be run by Linear Clinical Research (Linear) at its dedicated clinical trial facility in Perth, Western Australia. Linear will now commence the process of recruiting healthy volunteers into the trial. Dosing of the first cohort of volunteers is expected to commence in October.

Argenica CEO and Managing Director, Dr Liz Dallimore said: "We are delighted to receive ethics approval for our first-in-human study of ARG-007. This is a pivotal moment for Argenica, as we take ground-breaking research from the Perron Institute and the University of Western Australia into the clinic. We look forward to working with Linear on this trial and will provide regular updates as we progress through each cohort."

Clinical Trial Design

Up to 32 subjects will be dosed in the Phase 1 trial to be conducted at the Linear Clinical Research trial facility in Perth, Western Australia. Subjects will be randomly assigned to receive either ARG-007 or matching placebo (ratio 3:1 respectively) administered as a single

IV dose on Day 1. Both the site staff treating subjects and the subjects themselves will be blinded to the treatments being administered.

There will be 4 cohorts investigated in the study, with 8 participants in each cohort. Subjects will be enrolled into sequential cohorts with the first cohort receiving either the lowest dose of ARG-007 or a placebo. Following this, the next cohort will receive a slightly higher dose (or placebo), then so on.

Each cohort will include 2 sentinel subjects (1 assigned to ARG-007 and 1 assigned to placebo). The 2 sentinel subjects will be dosed 24 hours prior to the remaining subjects in the cohort and monitored for 24 hours. Should the dose be deemed to be safe and well tolerated after 24 hours by the investigator, the remaining 6 subjects in the cohort will be dosed.

Following dosing, safety, tolerability, PK, and immune response assessments will be performed for all participants in the cohort. Safety data will be reviewed by a Scientific Review Committee prior to dose escalation to the next dose ascending cohort.

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 improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007 has been successfully demonstrated to improve outcomes in pre-clinical stroke models and is in the process of being verified for its safety and toxicity before commencing Phase 1 clinical trials in humans. The aim is for our therapeutic to be administered by first responders to protect brain tissue against damage during a stroke with further potential to enhance recovery once a stroke has taken place.