ETHICS APPLICATION SUBMITTED TO SEEK APPROVAL TO COMMENCE PHASE 1 TRIAL

Highlights:

- *Argenica submits its ethics application seeking approval to commence its pivotal Phase 1 clinical trial of ARG-007 in healthy participants.*
- *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.*
- *Safety data will be reviewed by a Scientific Review Committee prior to dose escalation to the next dose ascending cohort.*

Perth, Australia; 11 AUGUST, 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 submission of the Company's ethics application to Bellberry's Human Research Ethics Committee (HREC) seeking approval to commence a Phase 1 healthy participant study of ARG-007.

The Phase 1 trial will be a Double-Blind, Randomized, Placebo-Controlled, Sequential-Group Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single Ascending Doses of ARG-007 in **healthy** participants.

The Company expects the HREC review to take approximately 4-6 weeks. Should approval be received from the HREC, recruitment of participants into the trial will commence through Linear Clinical Research.

Argenica CEO and Managing Director, Dr Liz Dallimore said: "We are excited to submit our ethics application to the HREC for approval of this first-in-human study of ARG-007. We have done everything we can to be in a position to commence the Phase I trial as soon as possible, should we receive HREC approval. The Company is entering an exciting stage progressing from a preclinical to a clinical company. The culmination of close to 10 years of scientific research on our lead candidate has led us to this moment and we are looking forward to the outcome of the submission in due course."

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.