

## PHASE 1 CLINICAL TRIAL SUMMARY

**Perth, Australia; 8 September 2022** – in addition to yesterday’s announcement “Argenica Receives Ethics Approval to Commence Phase 1 Trial”, Argenica Therapeutics Limited (ASX: AGN) (“Argenica” or the “Company”), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke, provides the following summary of its upcoming Phase 1 clinical trial.

<b>Title:</b>	A Phase 1, 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
<b>Investigational Product Name:</b>	ARG-007 (GMP)
<b>Clinical Research Organisation (CRO)</b>	Linear Clinical Research
<b>Study Centre:</b>	Linear Clinical Research facility, Perth, Western Australia
<b>Development Phase:</b>	Phase I
<b>Study Type:</b>	Double-blind, randomized, placebo-controlled
<b>Objectives and Endpoints:</b>	<p><b>Primary Objective:</b> To evaluate the safety and tolerability of single escalating doses of ARG-007:</p> <p><b>Secondary Objective:</b> To determine the pharmacokinetic profile of ARG-007 following single dose administration:</p> <p><b>Exploratory Objective:</b> To assess the immune response to ARG-007 following single dose administration:</p>
<b>Investigational Product Administration:</b>	Intravenous infusion over 10 minutes
<b>Inclusion Criteria:</b>	Any gender aged 18 to 65 inclusive at the time of screening; generally healthy with the exception of those medical conditions allowed as per the inclusion/exclusion criteria, body mass index 18.0 to 32.0 kg/m <sup>2</sup> , inclusive at the time of screening and Day -1; weight between 50.0 to 100.0 kg at the time of screening and at Day -1.

<b>Sample Size:</b>	The sample size for this study will be approximately 32 subjects. The sample size for this study has been selected without performing a formal sample size calculation.
<b>Study Design:</b>	<p>At least 32 subjects will be enrolled in this study at a single study center. Subjects will be randomly assigned to receive either investigational product 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.</p> <p>There will be 4 cohorts investigated in the study. Each cohort will include 2 sentinel subjects (1 assigned to ARG-007 and 1 assigned to placebo). Sentinel subjects will be dosed 24 hours prior to the remaining subjects in the cohort and monitored for 24 hours. Once the dose is deemed to be safe and well tolerated after 24 hours by the investigator, the remaining subjects in the cohort will be dosed.</p> <p>The study is designed as a dose escalation study. Dosing will commence with the lowest dose cohort (0.03 mg/kg ARG-007/placebo). Once at least 6 subjects in a given dose cohort completed dosing, safety data will be reviewed by a SRC prior to dose escalation to the next dose cohort.</p> <p>The study will consist of a screening period, treatment period and follow-up period.</p>
<b>Study Period</b>	up to 6 months

*This announcement has been approved for release by the Managing Director and Company Secretary*

For more information please contact: [info@argenica.com.au](mailto: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.