SUCCESSFUL COMPLETION OF FINAL PRE-CLINICAL PHARMACOKINETICS STUDY

Highlights:

- *Argenica successfully completes the full Pharmacokinetics (PK) study.*
- *The study is essential in determining how ARG-007 is absorbed, distributed, metabolised and excreted by the body, along with establishing appropriate dosing regimens for the upcoming Phase 1 clinical trial.*
- *Findings show favourable PK profiles in the dose range of 0.05 - 5 mg/kg, which includes ARG-007's efficacious dose range of approximately 1-3 mg/kg (in rodents).*
- *No adverse effects were observed in the animals, indicating that ARG-007 should be safe and well-tolerated in humans at pharmacodynamically relevant doses.*
- *The completion of this pharmacokinetics study is the final study required to finalise the Company's ethics submission.*

Perth, Australia; 19 MAY 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 completion of the final pharmacokinetic (PK) study of ARG-007 required for the Phase 1 clinical trial.

The rodent-based study has been essential in determining how ARG-007 is absorbed, distributed, metabolised, and excreted by the body. Findings from the study have also been instrumental in establishing appropriate dosing regimens for the upcoming Phase 1 clinical trial, and the data will now be incorporated into the ethics submission package.

POSITIVE RESULTS

The data generated from the PK study has shown favourable PK profiles in the dose range of 0.05 - 5 mg/kg which includes ARG-007's efficacious dose range of approximately 1-3 mg/kg (in rodents). The study showed that ARG-007 reached maximum concentration in the blood (irrespective of sex or dose) in rapid time, indicating a fast onset of therapeutic effect.

These results confirm ARG-007's PK profile as determined in the pilot study announced on 1 July 2021, and further supports previous data from a radiolabelled Positron Emission

Tomography (PET) imaging study showing ARG-007 is rapidly taken up by the kidneys - the standard route of peptide clearance from the body.

In addition to the measured PK data, no adverse effects were observed in the animals in each arm of the study. This data complements Argenica's already completed GLP safety and toxicology studies, indicating that ARG-007 should be safe and well-tolerated in humans at pharmacodynamically relevant doses.

Argenica's Chief Executive Officer, Dr Liz Dallimore said: "The completion of this full pharmacokinetics study is the final study required to finalise our ethics submission, allowing us to move closer to initiating our Phase 1 clinical trial. Achieving favourable PK profiles in this animal study complements the positive data we have in our safety and toxicology studies, allowing us to now focus on finalising the ethics submission required for approval to commence our Phase 1 clinical trial."

CLINICAL TRIAL UPDATE

Completion of the PK study now completes all studies required for ethics submission. The only outstanding item of work is the completion of the analysis of pathology samples from the GLP toxicology studies. This work was delayed due to the extensive lockdown in Shanghai impacting the Clinical Research Organisation's access to laboratories. The pathology analysis has now commenced and is expected to be completed in the coming weeks.

Following completion of the pathology analysis, Argenica will submit the required documentation to Bellberry's Human Research Ethics Committee (**HREC**) for review and approval to initiate the first-in-human Phase 1 clinical trial of ARG-007. The single site Phase 1 trial will be conducted at the Linear Clinical Research facility in Perth, Western Australia. The trial will be run as a dose escalating trial across four cohorts. Each cohort will comprise of 8 volunteers, with the first cohort receiving the lowest dose of ARG-007 or a placebo. Should that dosing show no adverse reactions, dosing of the next 8 volunteer cohort will commence. Given the sequential nature of the dosing of cohorts, preliminary results are expected to be announced throughout the trial following completion of dosing in each cohort. The trial is estimated to take approximately 6 months from HREC Approval to finalisation of the trial report.

The objectives of the Phase 1 clinical trial are to improve our understanding of how ARG-007 affects the body, evaluate the safety of ARG-007 when administered in humans, determine the ideal safe dosage and identify any possible adverse reactions. The data will also be critical to progress into a more comprehensive Phase 2 trial, where ARG-007 will be administered to stroke patients.

While stroke is the current corporate and commercial focus for the Company, safety data from the Phase 1 clinical trial can potentially be used to move directly into Phase 2 trials in other types of brain injury including hypoxic ischemic encephalopathy (HIE), traumatic brain injury (TBI), and surgically induced stroke.

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.