GLP SAFETY STUDIES SUCCESSFULLY COMPLETED, NO ABNORMAL SYMPTOMS OBSERVED

Highlights:

- *The GLP Safety studies required for the upcoming Phase 1 clinical trial ethics submission have been successfully completed.*
- *Studies assessed the effects of ARG-007 on the central nervous system, and respiratory system in rats, and the cardiovascular system in non-human primates.*
- *No abnormal symptoms were observed even at the maximum tolerated dose.*
- *This completes all required safety pharmacology studies needed for the Phase 1 clinical trial ethics submission.*

Perth, Australia; 5 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 the successful completion of its safety pharmacology preclinical studies, conducted under the Good Laboratory Practice (GLP) regulatory framework, with **no abnormal symptoms observed**. These studies are a key requirement for the Company's ethics submission for the upcoming Phase 1 clinical trial.

Safety pharmacology studies investigate the potential undesirable pharmacodynamic effects of a drug substance on physiological functions. The doses of ARG-007 assessed in these studies included doses in the therapeutic range and up to the maximum tolerated dose (MTD) determined in previous GLP toxicology studies. It is important to investigate the potential for undesirable pharmacological activity in appropriate animal models to incorporate monitoring for these activities in Argenica's clinical studies. The aim of the safety pharmacology studies is to reveal any adverse effects of a substance on the major physiological systems (e.g., cardiovascular, respiratory, and central nervous systems).

Argenica, through its preclinical contract research organisation, undertook the following three safety studies: rat behaviour safety pharmacology (functional observational battery), rat respiratory safety pharmacology, and non-human primate cardiovascular safety pharmacology studies, all under GLP conditions. Animals received doses of ARG-007 at the efficacious dose and up to the MTD.

All studies were completed successfully with **no abnormal symptoms observed** in any of the animals at any of the doses administered, including the MTD. Combined with the recent GLP toxicology studies which identified the MTD, these safety studies provide the Company with added confidence for the upcoming Phase 1 clinical trial.

Argenica's package of required preclinical safety study assessments required for ethics approval have now largely been completed, with the exception of final pathology assessment of the toxicology and the pharmacokinetic (PK) study. Argenica's clinical research organisation has recently informed the company that the in-life phase for the PK studies have now been completed and the bioanalysis has commenced, and data will be provided shortly.

Chief Executive Officer, Dr Liz Dallimore, said: "We are extremely encouraged by the results of these GLP safety pharmacology studies, which show that even at high doses of ARG-007, there were no abnormal effects seen. This gives us great confidence as we prepare our ethics submission to gain approval for our upcoming Phase 1 clinical trial."

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.