ARGENICA COMPLETES PILOT PRE-CLINICAL PHARMACOKINETICS STUDY

Highlights:

- *Highly encouraging results from Argenica's pilot Pharmacokinetic (PK) study, allowing the company to move closer towards its planned Phase 1 in-human clinical trial.*
- *Pharmacokinetic studies are critical in determining how ARG-007 reacts in the body and are essential for establishing appropriate dosing regimens for the Phase 1 trial.*
- ***No adverse effects were observed** in the PK animal study, indicating that ARG-007 is potentially safe and well-tolerated at the relevant doses.*
- *Argenica will now initiate studies required by the regulators for the Phase 1 clinical trial, including the full PK, genotoxicity, safety pharmacology and toxicokinetic studies.*

Perth, Australia; 1 JULY 2021 - 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 highly encouraging results from its pilot preclinical pharmacokinetic (PK) study for its lead therapeutic candidate, ARG-007.

The PK profile of a drug provides data to determine what happens to a drug in the body including a drug's absorption into the bloodstream, distribution to tissues, and how it is metabolised and/or excretion from the body.

An understanding of the PK of investigational drugs is essential for establishing appropriate dosing regimens and is an important element of the data package required to initiate the clinical development of ARG-007.

POSITIVE INITIAL RESULTS

The PK data generated has indicated favourable PK profiles in the dose range of 0.3-10 mg/kg which includes ARG-007's efficacious dose of approximately 1 mg/kg, with a rapid time to reach maximum concentration in the blood, irrespective of sex or dose. Argenica has completed this pilot PK study to confirm that ARG-007 has adequate PK parameters prior to initiation of final preclinical PK studies required for the Phase 1 clinical trial.

These results expand ARG-007's PK profile, which includes 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, indicating that ARG-007 is potentially safe and well-tolerated at the administered, pharmacodynamically relevant doses.

These results are necessary for the upcoming toxicology studies required for the clinical trial regulatory submission and will also provide insights into how ARG-007 could be clinically administered in stroke and other therapeutic applications.

Argenica's Chief Executive Officer, Dr Liz Dallimore said: "We are very pleased to see the positive results of our pilot pharmacokinetics studies in confirming the feasibility of our study design and protocols. Achieving favourable PK profiles in this animal study moves us a step closer to initiating our Phase 1 clinical trial for ARG-007. With this data, the company remains on track to initiate our Phase 1 clinical trial in Q4 2021."

CLINICAL TRIAL REMAINS ON TRACK FOR Q4 2021

Argenica is now focused on optimisation of the manufacturing processes and has formally initiated the studies required by the regulators for the Phase 1 clinical trial, including the full PK, genotoxicity, safety pharmacology and toxicokinetic studies.

The Phase 1 clinical trial will provide critical data related to the safety of ARG-007 in healthy subjects, which is required for a more comprehensive Phase 2 study in stroke patients. The Company aims to release further information and an overview of its clinical trial in the near term.

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.