MAXIMUM TOLERATED DOSE SUCCESSFULLY ESTABLISHED IN FINAL GLP TOXICOLOGY STUDIES

Highlights:

- *Final Good Laboratory Practise (GLP) Toxicology studies have determined the maximum tolerated dose of ARG-007 required for the Phase 1 clinical trial.*
- *GLP toxicology studies carried out in rats and non-human primates collected key data required for ethics approval of the upcoming Phase 1 clinical trial.*
- *The maximum tolerated dose established in these studies is significantly higher than doses to be used in the Phase 1 clinical trial, thereby reducing the likelihood of an adverse event occurring during the Phase 1 trial.*

Perth, Australia; 26 APRIL 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 results of in-life rodent and non-human primate toxicology studies which have established the maximum tolerated dose (MTD) of ARG-007, which is a key requirement for the Phase 1 clinical trial ethics approval.

Toxicology studies conducted under the Good Laboratory Practice (GLP) qualify framework are required by the regulatory bodies to understand the toxicology profile of a new drug prior to it being administered in humans. These studies determine the onset, degree of severity, and length of time in which a particular dose of a drug demonstrates any toxic effects. Argenica's single-dose extended GLP toxicology studies, conducted in both rats and non-human primates, included a recovery phase to assess delayed toxicity and/or recovery. The data collected, all of which play a pivotal role in the toxicology assessments, comprised of mortality and clinical observational data, toxicokinetics, hematology blood clinical chemistry analysis, urinalysis, and necropsy data.

These toxicology studies have determined ARG-007's MTD is up to 10 times the efficacious dose range identified in animals, and provides a desirable safety margin to establish the safe starting dose in the Phase 1 clinical trial. Importantly, this reduces the likelihood of a serious adverse event occurring during the Phase 1 trial. The findings from these final toxicology studies will be a key inclusion in the Company's submission to the Human Research Ethics Committee for approval of the Phase 1 clinical trial.

The Company is now completing the final pathology assessments, along with final safety studies using the MTD determined, for inclusion in the Company's ethics submission.

Chief Executive Officer, Dr Liz Dallimore, said: "The results of the GLP toxicology data demonstrate that ARG-007 has a good safety margin from the efficacious dose to the maximum tolerated dose. This gives us added confidence that we will be able to achieve ethics approval for the 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.