ARGENICA RECEIVES POSITIVE FEEDBACK ON ARG-007 FOLLOWING PRE-IND MEETING WITH FDA

Highlights:

- *Argenica has received positive feedback and guidance from the US Food and Drug Administration (FDA) on its clinical development program of ARG-007 under a pre-investigational new drug type B meeting request (pre-IND meeting).*

- *The guidance includes a review of Argenica's Chemistry, Manufacturing and Controls (CMC) program, preclinical efficacy data, safety and toxicology data, and clinical trial program.*

- *The FDA's feedback confirmed the Phase 2 trial protocol assessing ARG-007 in acute ischaemic stroke patients was acceptable to assess preliminary efficacy (proof-of-concept) of ARG-007.*

- *The positive guidance gives Argenica confidence as it progresses into a Phase 2 clinical trial of ARG-007 in acute ischemic stroke patients.*

Perth, Australia; 23 AUGUST 2023 - 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 that it has received positive feedback and guidance from the US Food and Drug Administration (FDA) on the clinical development program of ARG-007 as a neuroprotective treatment for acute ischaemic stroke via a pre-investigational new drug type B meeting (pre-IND meeting).

The primary purpose of a pre-IND meeting with the FDA is to obtain feedback on the design of preclinical studies, the design of clinical studies, and product manufacturing and quality controls needed to initiate human studies in the US.

Argenica provided to the FDA a detailed briefing document which included details and specific questions regarding ARG-007's preclinical development and proposed Phase 2 clinical trial.

Argenica sought feedback and guidance on the appropriateness of the chemistry, manufacturing and controls (CMC) for ARG-007, as well as feedback and guidance on the completed preclinical studies and proposed Phase 2 trial protocol. The FDA responded in writing (as is now becoming standard practice for pre-IND meetings) and the feedback

received from the FDA was positive. The FDA indicated that the studies conducted to date were appropriate for the stage of development and the proposed Phase 2 clinical trial protocol was acceptable in regard to assessing the preliminary efficacy (proof of concept) and safety of ARG-007 in acute ischaemic stroke patients. The feedback provides Argenica further confidence as it progresses ARG-007 into a Phase 2 clinical trail in acute ischemic stroke patients, and ultimately into a Phase 3 trial in the US.

Argenica's Managing Director, Dr Liz Dallimore said: "The positive feedback we've received from the FDA is extremely encouraging and provides the Company with great confidence as we progress ARG-007 into a Phase 2 clinical trial in acute ischaemic stroke patients at the end of this calendar year. The feedback provides the Company with a confirmed path for clinical development of ARG-007."

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 other types of brain injury and neurodegenerative diseases to improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007, has been successfully demonstrated to improve outcomes in pre-clinical stroke models, traumatic brain injury (TBI) and hypoxic ischaemic encephalopathy (HIE). The Company has recently completed a Phase 1 clinical trial in healthy human volunteers to assess the safety and tolerability of a single dose of ARG-007. Argenica is now progressing towards a Phase 2 clinical trial in ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions, including in TBI, HIE and Alzheimer's Disease.