ASX ANNOUNCEMENT

UPDATE ON ARGENICA'S US FDA IND APPLICATION

Perth, Australia; 10 June, 2025 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other neurological conditions, has received correspondence from the United States (US) Food and Drug Administration (FDA) that it has placed a clinical hold on the Company's Investigational New Drug (IND) Application. The FDA has indicated that the non-clinical data package provided in the IND is not adequate to support initiation of a proposed Acute Ischaemic Stroke (AIS) trial in the US at this time.

No further details on the FDA's additional requirements have been provided at this time, however the Company expects further detailed correspondence from the FDA within 30 days. It is important to note that this correspondence from the FDA **does not impact the current Phase 2 clinical trial being conducted in Australia, which is on track for data readout in Q3 CY2025.**

Argenica had anticipated there may be some challenges in receiving an open IND within the 30-day time period due to current resourcing challenges at the FDA, hence the decision to submit the AIS IND application much earlier than required to actually start anticipated future clinical trials in the US. Notwithstanding that within the submitted IND the Company had addressed all requests by the FDA for non-clinical information outlined in its pre-IND type B meeting[1], the Company is committed to providing any additional specific data that the FDA may require.

Dr Liz Dallimore, **Managing Director of Argenica**, commented*: "Whilst we are obviously disappointed with the hold placed on our AIS IND application, we are confident we can provide the additional data required by the FDA in a timely manner and move towards opening our AIS IND in the near future. We will keep the market informed once we know the nature of the FDA's additional requirements".*

This announcement has been approved for release by the Board of Argenica

For more information please contact: info@argenica.com.au

[1] ASX Announcement dated 23 August, 2023

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 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 undertaking a Phase 2 clinical trial in acute ischaemic stroke patients, with dosing in this trial now complete, as well as continuing to generate preclinical data in other neurological conditions.