FDA GRANTS ORPHAN DRUG DESIGNATION FOR ARG-007 TREATMENT OF HIE

Perth, Australia; 15 NOVEMBER 2023 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after brain injury and other neurological conditions, is pleased to announce the Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) status to ARG-007 for the treatment of Hypoxic Ischaemic Encephalopathy (HIE).

Supporting the development and evaluation of new treatments for rare diseases is a key priority for the FDA. The FDA has authority to grant ODD to a drug or biological product to prevent, diagnose or treat a rare disease or condition. ODD qualifies companies for incentives including:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after approval

Argenica recently announced further encouraging preclinical data on the potential of ARG-007 in reducing brain injury following HIE[1], showing ARG-007 significantly reduces brain cell death in animal models of HIE. The Company is continuing to complete all required studies to progress into clinical trials in HIE.

HIE occurs when the brain does not receive enough oxygen or blood flow for a period of time. It may occur at any time prior to labour, during labour and delivery, or immediately following delivery. The initial injury that is caused by a loss or reduction of oxygen supply is followed by progressive brain cell death due to excitotoxicity, oxidative stress, and inflammation[2,3]. The physiological effects resulting from the interruption to blood flow and/or oxygen in the brain can vary greatly depending on the length of time the disruption occurs as well as the location of the disruption. Some children may only display mild effects whilst others will have severe permanent disability including cerebral palsy, cognitive impairment, or developmental delay.

Dr Liz Dallimore, **Argenica's Managing Director**, said: "The granting of Orphan Drug Designation for ARG-007 in HIE forms a key pillar of Argenica's commercialisation strategy.

[1] ASX Announcement dated 18 October, 2023.
[2] Leonardo CC, Pennypacker KR. Neuroinflammation and MMPs: potential therapeutic targets in neonatal hypoxic-ischemic injury. *J Neuroinflammation* (2009) 6:13
[3] Thornton C, Hagberg H. Role of mitochondria in apoptotic and necroptotic cell death in the developing brain. *Clin Chim Acta* (2015) 451:35–8

The potential for extensive market exclusivity following approval of ARG-007 is an extremely compelling commercial driver for the Company. We look forward to continuing to progress the development of ARG-007 as a treatment for HIE in newborn infants, in which there are currently no therapeutic drugs available to treat this devastating condition."

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.