FDA GRANTS ARGENICA RARE PEDIATRIC DISEASE DESIGNATION FOR ARG-007 IN TREATMENT OF HIE

Perth, Australia; 25 MARCH 2024 - 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 United States Food and Drug Administration (FDA) has granted its neuroprotective drug ARG-007 **Rare Pediatric Disease Designation (RPDD**) for the treatment of Hypoxic Ischaemic Encephalopathy (HIE) in newborn term infants.

Supporting the development and evaluation of new treatments for rare diseases in children is a key priority for the FDA. The FDA has authority to grant a RPDD to a drug or biological product that shows promise in preventing, diagnosing or treating a rare disease or condition in the pediatric population (children 18 years and younger). The granting of the RPDD provides one key substantial benefit to Argenica, being, that upon approval of a New Drug Application (NDA) for ARG-007 in HIE, the FDA may award a **Priority Review Voucher (PRV)** provided that HIE is the first indication for which the drug is approved. The voucher can be redeemed to accelerate the review of a subsequent marketing application or may be sold or transferred to a third party. The sale price of a PRV is often in the tens of millions of dollars[1].

This RPDD is in addition to the benefits granted to Argenica under the Orphan Drug Designation program, announced on 15 November 2023, in which the Company will receive greater guidance from the FDA during the clinical development of ARG-007 in HIE, as well as the potential for seven years of market exclusivity in the US following approval[2].

Argenica recently announced further encouraging preclinical data on the potential of ARG-007 in reducing brain injury following HIE[3], showing ARG-007 significantly reduces brain cell death in animal models of HIE. The Company is continuing to develop a program of work to validate ARG-007 as a prospective treatment for HIE in newborn infants.

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

[1] https://www.linkedin.com/pulse/speeding-success-lucrative-market-fda-priority-review-vouchers-1bg4c/
[2] ASX Announcement dated 15 November, 2023.
[3] ASX Announcement dated 18 October, 2023.

progressive brain cell death due to excitotoxicity, oxidative stress, and inflammation[4,5]. 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: "This further validation by the FDA on the potential of ARG-007 in HIE through the granting of a Rare Pediatric Disease Designation is extremely encouraging. There are currently no therapeutic drugs available to treat this devastating condition. This RPDD will provide the Company with potential significant upside at the end of a clinical program in HIE to receive a priority review to get the drug on the market quickly, or the option to sell the voucher to a third party. We look forward to continuing to progress the development of ARG-007 as a treatment for HIE in newborn infants"."

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.

[4] Leonardo CC, Pennypacker KR. Neuroinflammation and MMPs: potential therapeutic targets in neonatal hypoxic-ischemic injury. *J Neuroinflammation* (2009) 6:13

[5] Thornton C, Hagberg H. Role of mitochondria in apoptotic and necroptotic cell death in the developing brain. *Clin Chim Acta* (2015) 451:35–8