SUCCESSFUL APPLICATON FOR EMA PAEDIATRIC WAIVER FOR ARG-007 IN STROKE

Highlights:

- *Argenica has **been successful** in its application to the European Medicines Agency (EMA) seeking **a full waiver to develop ARG-007 in paediatric acute ischaemic stroke** (AIS), which is an uncommon condition in children.*

- *Argenica's Product-Specific Waiver to submit a Paediatric Investigational Plan (PIP) for all subsets of the paediatric population **removes the regulatory obligation to conduct paediatric trials in AIS** as part of a European Marketing Authorisation Application.*

- *Obtaining a PIP waiver for ARG-007 in stroke is **a critical regulatory step** because it allows Argenica to progress through the EMA approval pathway for ARG-007 in adult AIS without being required to conduct paediatric clinical studies in order to have the drug approved.*

- ***This approval significantly streamlines and de-risks** the European development pathway for ARG-007 in AIS by reducing development burden and cost and supports a more efficient path toward potential market registration in the European Union.*

Perth, Australia; 2 February, 2026 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other acute neurological conditions, is pleased to advise that the European Medicines Agency (EMA) has granted a full Product Specific waiver for the Company's lead neuroprotective drug candidate, ARG-007, for the treatment of paediatric acute ischaemic stroke (AIS), a rare occurrence in children and clinical studies are not feasible.

Obtaining a Product Specific waiver for ARG-007 in stroke is a critical regulatory step because it allows Argenica to progress through the EMA approval pathway without being required to conduct paediatric clinical studies—studies that are not scientifically justified in the context of stroke. Ischaemic stroke is overwhelmingly a condition of older adults, and paediatric stroke is rare, making clinical studies not feasible. As a result, mandating paediatric trials would add years of development time, significant cost, and regulatory complexity while providing no meaningful clinical value.

Under the EMA regulatory approval pathway, all new drugs seeking approval in Europe are required to conduct paediatric trials unless a waiver is granted on the grounds of one of the following:

- medicines that are likely to be ineffective or unsafe in part or all of the paediatric population;
- medicines that are intended for conditions that occur only in adult populations;
- medicines that do not represent a significant therapeutic benefit over existing treatments for paediatric patients, including conducting studies are impossible or highly impracticable.

When seeking approval in the EU, drug sponsors **must** have an agreed PIP—or a formal waiver—in place before submitting a marketing authorisation application (MAA) for a drug in an adult condition. Failing to secure a waiver when appropriate can add significant, unnecessary cost, time, and complexity.

The waiver, which applies to all subsets of the paediatric population from birth to less than 18 years of age, was recommended by the Paediatric Committee (PDCO) of the EMA and subsequently approved by the Agency. It confirms that no paediatric clinical studies will be required to support a future MAA in Europe for ARG-007 in AIS.

This outcome reduces development burden and cost and supports a more efficient path toward potential market registration in the European Union.

Argenica Managing Director, Dr Liz Dallimore, commented: "We are very pleased to have received a full paediatric waiver from the EMA for ARG-007 in AIS. This decision confirms that paediatric studies are not required for this indication and represents a key milestone in our global regulatory strategy. The waiver allows us to streamline our European development program and maintain our focus on progressing ARG-007 for adult stroke patients as quickly as possible. This will also be seen as a real positive for future potential pharmaceutical company partners."

ABOUT THE PAEDIATRIC INVESTIGATION PLAN (PIP)

Under the European Paediatric Regulation introduced in 2007, pharmaceutical companies developing medicines for adult conditions must reach agreement with the EMA on a **Paediatric Investigation Plan** (PIP) unless a waiver is granted. A PIP outlines the studies required to support the use of a medicine in children.

A **full waiver** may be granted when certain conditions, outlined above, are met. For acute ischaemic stroke, the EMA determined a waiver was justified on the on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

From a commercial and operational perspective, a PIP waiver offers three major advantages:

1. Faster Path to Market in Europe
Without a waiver, EMA approval cannot proceed to marketing authorisation until paediatric obligations are completed, paused, or waived. Securing a waiver early prevents delays at the time of NDA/MAA submission and ensures the regulatory timeline remains aligned with the adult stroke program.

2. Lower Development Costs
Paediatric studies in stroke would be extremely difficult to run, given the rarity of the condition, and would require global site activation, specialised monitoring, and long enrolment periods. A waiver avoids significant, unnecessary expenditure and preserves capital for studies that directly contribute to ARG-007's adult stroke approval.

3. Regulatory Clarity and Reduced Risk
A PIP waiver provides certainty that the regulatory requirements for ARG-007 in Europe are focused solely on adult stroke. This removes a large source of potential regulatory risk, simplifies interactions with the EMA, and gives investors greater confidence in projected timelines and costs.

NEXT STEPS

Argenica continues to advance the clinical development program for ARG-007 in adult AIS and is progressing discussions with regulatory agencies in key global markets.

This announcement has been approved for release by the Managing Director & Company Secretary.

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

ABOUT ARGENICA

Argenica Therapeutics Limited (ASX: AGN) is a clinical-stage biotechnology company developing innovative neuroprotective therapeutics to improve outcomes for patients following stroke and other acute neurological injuries. The Company's lead drug candidate, ARG-007, is designed to protect vulnerable brain tissue by reducing cell death and limiting secondary damage after an ischemic event. With a strong scientific foundation and a clear clinical development pathway, Argenica is focused on advancing novel treatments that have the potential to significantly improve patient recovery and transform the standard of care in acute neurology.