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ARG-007 (XARANETIDE) COMPLETES ALL THREE FDA REQUESTED ASSAYS WITH CLEAN SAFETY PROFILE IN CARDIAC ASSAY

KEY HIGHLIGHTS

- *ARG-007 (xaranetide) has directly addressed the **third and final FDA clinical hold requirement** related to safety assays by successfully completing a fully GLP-compliant in vitro hERG assay, showing **no statistically significant inhibition of the hERG cardiac potassium channel** at the highest testable concentration.*

- *The hERG potassium channel plays a central role in cardiac electrical activity. Inhibition of this channel by drug compounds has historically been associated with potentially life-threatening cardiac arrhythmias, including sudden cardiac death. The lack of inhibition of this channel **supports a favourable safety profile of ARG-007 (xaranetide) in cardiac tissue.***

- *All three FDA-requested assays are now complete, **with all three demonstrating clean and favourable safety profiles.***

- *Following finalisation of the Phase 2b protocol in the coming weeks, Argenica will be well positioned to submit a comprehensive response to the FDA clinical hold and seek approval of the IND for ARG-007 (xaranetide), a pivotal step toward commencing the Phase 2b clinical trial in acute ischaemic stroke patients.*

Perth, Australia; 11 JUNE 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 announce results of the hERG assay, conducted under good laboratory practice (GLP), showing ARG-007 (xaranetide) does not inhibit the hERG cardiac potassium channel, indicating a clean safety profile of ARG-007 (xaranetide) in cardiac tissue.

Dr Liz Dallimore, Managing Director of Argenica, commented: *"Completing the GLP hERG assay is a significant milestone for Argenica and for ARG-007 (xaranetide). The FDA specifically identified the absence of a hERG study as a deficiency preventing clinical progression, and we have now addressed that requirement with a clean, fully GLP-compliant result showing essentially no cardiac liability at the highest testable concentration. Combined with the*

previously completed TNK assay and genotox assay, we have now successfully completed all of the FDA requested assays. We are firmly on track to compile our comprehensive response to the FDA and take the next steps toward lifting the clinical hold."

BACKGROUND — FDA CLINICAL HOLD

As previously disclosed to the market[1], Argenica received an IND clinical hold letter from the US Food and Drug Administration (FDA) in relation to ARG-007 (xaranetide). The clinical hold was issued due to identified issues applicable to **21 CFR 312.42(b)(2)(i): Insufficient information to assess risks to human subjects**.

The FDA's letter identified three specific areas to be addressed through the provision of additional *in vitro* data in relation to safety before the clinical hold can be lifted. In relation to cardiac safety, the FDA stated: *"A hERG assay was not submitted for ARG-007 (xaranetide). To address this deficiency, you would need to conduct a GLP-compliant in vitro hERG assay."*

Argenica has now **directly and conclusively addressed this specific FDA requirements**. The Company previously announced the completion of the TNK assay and the genotox assay, which were the other two FDA-requested studies. The hERG assay represents the third and final required study.

With the completion of this assay, and the soon to be finalised Phase 2b protocol, Argenica will be in a position to submit a comprehensive response to the FDA clinical hold in the coming week, with the aim of opening the IND for ARG-007 (xaranetide), enabling clinical studies to commence in the US.

hERG STUDY OVERVIEW

The GLP-compliant, in vitro hERG study was conducted by B'SYS GmbH (Switzerland), an internationally accredited safety pharmacology laboratory, using the whole-cell patch-clamp technique on CHO cells stably expressing the hERG channel at near-physiological temperature (35°C–37°C), fully consistent with FDA ICH S7B guideline requirements.

What is the hERG assay and why does it matter?

The hERG (human Ether-à-go-go Related Gene) potassium channel plays a central role in cardiac electrical activity. Inhibition of this channel by drug compounds has historically been associated with potentially life-threatening cardiac arrhythmias, including sudden cardiac death. Several approved drugs have been withdrawn from the market due to hERG-related cardiac toxicity, making a clean hERG profile one of the most critical non-clinical safety requirements regulators impose before permitting human clinical trials to proceed.

Results

At the highest testable concentration of 1 µg/mL, ARG-007 (xaranetide) produced a remaining hERG current amplitude of **100.74 ± 1.44%** (mean ± SEM, n=4) — effectively 100% of baseline

[1] ASX Announcement dated 14 August, 2025 "Argenica Receives IND Feedback from FDA."

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cardiac channel activity, demonstrating that ARG-007 (xaranetide) does not meaningfully interact with the hERG channel.

Statistical analysis confirmed that this result was **not significantly different from vehicle control** (P = 0.0524, P > 0.05), which itself showed a remaining current of 96.48 ± 1.02%. Critically, because ARG-007 (xaranetide) blocked less than 30% of hERG current amplitude at the highest testable concentration, **no IC_{50} (inhibitory concentration) could be calculated** — meaning that the concentration at which ARG-007 (xaranetide) would produce meaningful cardiac channel inhibition is beyond the measurable range of the assay. This is an exceptionally favourable outcome, reflecting the very low cardiac liability of the compound.

The study's validity was confirmed by the positive control compound Moxifloxacin, which produced the expected concentration-dependent hERG inhibition consistent with its known cardiac pharmacology (remaining current: 73.14 ± 2.07% at 30 µM and 38.87 ± 2.56% at 150 µM), demonstrating the sensitivity and reliability of the assay system.

PATH TO LIFTING THE FDA CLINICAL HOLD

Upon finalisation of the Phase 2b protocol in the coming weeks, Argenica intends to compile and submit a comprehensive response to the FDA addressing all identified requirements. The clinical hold response will include an updated Phase 2b protocol reflecting the focus on moderate to severe stroke patients, as well as an updated investigational brochure reflecting the changes to the proposed clinical development program. A successful FDA response would result in the lifting of the clinical hold and reinstatement of the IND, enabling Argenica to progress ARG-007 (xaranetide) into human clinical trials in the United States.

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

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 (xaranetide), 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.

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