13 July 2026

ASX Announcement

Texas Biomed agreement to further advance Galidesivir towards pivotal FDA Animal Rule study

- **Statement of Work executed with Texas Biomed to enhance Galidesivir dose optimisation initiatives prior to planned pivotal FDA Animal Rule efficacy study**
- **Texas Biomed is a leading, independent, non-profit infectious disease institute in the US with integrated National Primate Research Centre capabilities**
- **SOW provides opportunity to advance complementary FDA-directed dose optimisation study in a further 12 non-human primates**
- **Second FDA-directed study complements ongoing USAMRIID program by evaluating initiation of Galidesivir treatment on days that correlate with onset of clinical signs of infection, providing dose optimisation data across multiple treatment windows**
- **NHPs to be evaluated against FDA-preferred Angola strain of Marburg – study works to commence in October with infection study to begin in January 2027**
- **Complementary dose optimisation studies expected to materially de-risk dose selection and pivotal study design**
- **Dose optimisation study alongside expected to commence this quarter**
- **Combined studies to generate data from 32 NHPs for submission to the FDA, materially strengthening dose selection, pivotal study design and overall Animal Rule regulatory package**
- **Additional animal cohort also secured, providing operational flexibility while maintaining development momentum towards pivotal Animal Rule studies**

MELBOURNE Australia, 13 July 2026: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to advise that it has executed a Statement of Work (SOW) with the Texas Biomedical Research Institute (Texas Biomed) to further advance Galidesivir's Animal Rule development (refer ASX announcement: 4 February 2026) for the treatment of Marburg Virus Disease.

The SOW, executed under the existing Master Services Agreement between Island and Texas Biomed (refer ASX announcement: 17 December 2025), establishes the second phase of the Company's dose optimisation program, a key component of the regulatory package required to support the design of Galidesivir's planned pivotal Animal Rule efficacy study.

The program has been designed in accordance with feedback from the U.S. Food and Drug Administration (FDA), which confirmed Galidesivir's regulatory pathway under the Animal Rule and recommended the completion of dose optimisation studies before finalising the pivotal study design.

The Company's dose optimisation program commenced under Island's Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) (refer ASX announcement: 10 June 2026).

The execution of the Texas Biomed SOW expands this program through a complementary study at a second biosafety level 4 (BSL-4) facility, with the combined studies expected to generate the data required to optimise dose selection and finalise the design of the Company's planned pivotal Animal Rule efficacy study.

The Texas Biomed study represents the second phase of Island's FDA-directed dose optimisation program and has been designed to complement the ongoing USAMRIID study. While the USAMRIID program is evaluating the minimally effective dose when treatment is initiated 24 to 48 hours following infection, the Texas Biomed study will assess Galidesivir when treatment commences on days that correlate with first signs of clinical viral disease, typically between 3 and 5 days following infection.

Collectively, the studies are expected to generate the pharmacokinetic, efficacy and treatment timing data required to identify the minimally effective dose, optimise pivotal study parameters and strengthen the regulatory package for discussions with the FDA ahead of the planned Animal Rule efficacy study.

Under the terms of the SOW, Texas Biomed will evaluate Galidesivir in 12 non-human primates infected with the Angola strain of Marburg virus, the FDA-preferred challenge strain for Animal Rule development. Animal preparation activities are expected to commence in Q4 2026, with the challenge and treatment phase scheduled to begin in early 2027.

Texas Biomed is one of only four BSL-4 facilities in the United States capable of conducting non-human primate infectious disease studies and is the only privately operated BSL-4 laboratory. Its specialised capabilities in high-consequence pathogens, including Marburg virus, make it a globally recognised partner for the development of medical countermeasures against emerging infectious diseases.

Importantly, the agreement also secures access to a second cohort of animals should additional optimisation work be required following completion of the initial dosing optimisation studies, materially de-risking the program, while providing operational flexibility and maintaining development momentum towards commencement of the Company's planned pivotal Animal Rule efficacy study.

Management commentary:

Cory Hallam, Ph.D., Executive Vice President, Applied Science and Innovation at Texas Biomed, said: *"Texas Biomed serves as a critical national resource for evaluating medical countermeasures against high-consequence infectious diseases. Our decades of experience, advanced high-containment laboratories and specialised non-human primate research capabilities enable us to help move promising therapies toward clinical development. This partnership with Island Pharmaceuticals underscores Texas Biomed's role in supporting government and industry partners in the United States and around the world as we work together to strengthen global biodefense preparedness."*

Chief Executive Officer and Managing Director, Dr David Foster, said: *"Working with an institution of Texas Biomed's calibre represents another important milestone for Island and reflects the quality of the partners supporting the development of Galidesivir. As one of the world's leading high-containment infectious disease research organisations, Texas Biomed brings exceptional expertise to a program targeting one of the most significant unmet needs in emerging infectious diseases and global biodefence.*

Marburg virus remains a recognised bioterrorism threat with no broadly available approved antiviral treatments, making it essential that we execute a disciplined and scientifically rigorous development program.

The FDA has provided a clear roadmap to advance Galidesivir under the Animal Rule, and these complementary dose optimisation studies are a critical part of that pathway. By investing the time now to optimise dose selection and pivotal study design, we expect to materially de-risk the program before progressing into the pivotal efficacy study.

Our objective is to enter pivotal development with the strongest possible scientific and regulatory foundation, maximising the probability of a successful outcome while continuing to build the long-term value of the Galidesivir program."

Q&A

What is the purpose of the Texas Biomed study and how does it fit into Island's broader development program?

The Texas Biomed study represents the second phase of Island's FDA-directed dose optimisation program, complementing the ongoing USAMRIID Cohort 1 study. While USAMRIID is focused on identifying the minimally effective dose at 24–48 hours post-infection, Texas Biomed will evaluate Galidesivir when treatment is initiated on days that correlate with first clinical signs of infection, typically day 4–5, in 12 NHPs infected with the FDA-preferred Angola strain.

Why is Texas Biomed an important partner for this work?

Texas Biomed is one of only four BSL-4 facilities in the United States capable of conducting NHP studies with Marburg virus, and the only privately operated BSL-4 laboratory. Its integrated National Primate Research Center capabilities and decades of high-containment expertise make it a globally recognised centre for medical countermeasure development.

How does this study differ from the USAMRIID Cohort 1 program?

USAMRIID Cohort 1 evaluates Galidesivir dosing early after infection (24 or 48 hours), using multiple loading and maintenance regimens to determine the lowest effective dose. Texas Biomed Cohort 2 evaluates dosing at symptom onset (day 4–5), reflecting a clinically relevant treatment window for real-world emergency use. Together, the studies bracket the full spectrum of treatment timing required by the FDA.

Why is the Angola strain of Marburg significant?

The Angola strain is the FDA-preferred challenge strain for Animal Rule development due to its uniformly lethal profile and relevance to national security. Both USAMRIID and Texas Biomed will be using this strain to ensure regulatory alignment and maximise translational relevance for pivotal study design.

How many animals will be used, and why is this number important?

Texas Biomed will evaluate 12 NHPs, complementing the 20 NHPs secured under the USAMRIID CRADA. Securing multiple cohorts is strategically important because NHP availability is the single most constrained resource in the biodefence ecosystem. The agreement also secures access to a second cohort if additional optimisation work is required or may otherwise be utilised to progress Sudan virus through the same animal rule program.

What specific questions will the Texas Biomed study answer?

The study is designed to determine:

- The optimal treatment window at symptom onset
- The efficacy of Galidesivir when administered on days that correlate with first sign of viral infection symptoms, typically occurring between day 3 and 5 after infection
- The PK profile under later-stage treatment
- Comparative outcomes against placebo controls These data complement early-treatment optimisation from USAMRIID.

Why is a second dose optimisation study necessary?

The FDA recommended completing dose optimisation studies before finalising pivotal design. Conducting two complementary studies across two BSL-4 facilities materially de-risks dose selection, strengthens regulatory alignment, and ensures the pivotal study is built on the strongest possible scientific foundation.

When will the Texas Biomed study begin?

Animal preparation activities commence in Q4 2026, with infection and treatment scheduled for January 2027. This timeline allows Island to maintain continuous development momentum while USAMRIID Cohort 1 progresses this quarter.

How do these studies support the FDA Animal Rule pathway?

The Animal Rule requires:

- A well-characterised lethal challenge model
- Demonstrated survival benefit
- PK/PD bridging to human dosing The combined USAMRIID and Texas Biomed studies provide the survival, PK, timing, and dose-response data required to design and justify the pivotal confirmatory efficacy study.

What is the expected impact on pivotal study design?

Together, the studies will define:

- The minimally effective dose
- The optimal loading and maintenance regimen
- The appropriate treatment window
- The challenge strain and model parameters This enables Island to enter pivotal development with a fully optimised, FDA-aligned protocol.

How does this agreement de-risk Island's development pathway?

The Texas Biomed SOW:

- Secures a second NHP cohort
- Provides operational redundancy
- Ensures continuity of development
- Strengthens Island's position within the US biodefence ecosystem This materially reduces the risk of delays or bottlenecks in the Animal Rule program.

How do these studies support future US government procurement?

All modern biodefence countermeasures approved under the Animal Rule have progressed to Strategic National Stockpile (SNS) procurement, with average lifetime contract values of ~US$467m. Galidesivir's strong NHP survival history and alignment with FDA guidance position it as a compelling candidate for future procurement.

What is the commercial significance of advancing toward pivotal development?

Pivotal Animal Rule approval unlocks:

- Eligibility for a Priority Review Voucher (PRV) (~US$200m value)
- Potential SNS procurement
- International government contracts
- Expansion into additional filovirus indications (Ebola, Sudan virus) This represents a transformational commercial inflection point for Island.

How does Texas Biomed's involvement strengthen Island's biodefence positioning?

Texas Biomed's participation reflects the calibre of partners supporting Galidesivir's development. Their BSL-4 capabilities, NHP expertise and role as a national biodefence resource reinforce Island's credibility and deepen engagement across the US government biodefence network.

What are the next major milestones investors should watch?

Key upcoming catalysts include:

- Commencement of USAMRIID Cohort 1
- Announcement of Survival results from USAMRIID's Cohort 1 study
- Initiation of Texas Biomed Cohort 2 preparation
- PK/PD and survival readouts
- Finalisation of pivotal study design
- PRV-related updates
- Government partnership and procurement developments These milestones collectively advance Galidesivir toward pivotal Animal Rule approval.

- Ends –

Approved for release to the ASX by the Board.

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About Island Pharmaceuticals

Island (ASX: ILA) is focused on areas of unmet need for drugs that can address urgent viral diseases, public health or biosecurity threats. The Company is executing a dual development strategy for its assets, ISLA-101 and Galidesivir.

ISLA-101 has a well-established safety profile, being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases. Galidesivir is a clinical-stage antiviral molecule with a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Ebola, Marburg, MERS, Zika and Yellow fever – viruses with significant unmet medical needs and that may contribute to national security threats.

Island encourages all current investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.

Visit www.islandpharmaceuticals.com for more on Island.