4 February 2026

ASX Announcement

FDA confirms Galidesivir development pathway, unlocking accelerated approval route

- **FDA provides clear alignment on Galidesivir's Animal Rule development pathway, validating Island's proposed Marburg model**
- **Two-stage development sequence established, significantly de-risking approval and enabling rapid progression to pivotal confirmatory phase**
- **Targeted dose optimisation and PK studies to commence immediately using Island's first manufactured batch of Galidesivir**
- **Engagement with Texas Biomedical Research Institute (BSL-4) well progressed, with additional partners under advanced negotiation to accelerate timelines**
- **FDA feedback follows confirmation of Animal Rule approval pathway and Galidesivir's Priority Review Voucher (PRV) eligibility**
- **Last traded PRV was valued at ~US$200m, providing a significant value lever**
- **Correspondence reinforces Galidesivir's potential as a critical countermeasure for US biodefence and Strategic National Stockpile procurement**
- **Investor webinar scheduled 11:00am (AEDT) on Thursday, 5 February**

MELBOURNE Australia, 4 February 2026: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) advises it has received highly constructive and strategically important guidance from the US Food & Drug Administration (FDA), confirming the validity of Island's proposed animal model and outlining final steps required to progress Galidesivir toward approval under the Animal Rule.

The FDA's correspondence, received 30 January 2026 provides clear regulatory alignment on the use of the Angola strain of Marburg, the cynomolgus macaque model and the viral challenge dose – the core elements that underpin Animal Rule development. This confirmation represents a major de-risking milestone for the program.

The FDA has now defined a two-stage clinical development pathway for Galidesivir, enabling Island to move rapidly into targeted dose-optimisation and pharmacokinetic (PK) studies, followed by a pivotal confirmatory study required for approval.

Island will advance a short-term dose optimisation and PK analysis followed by a time-to-dose study to determine the optimal treatment window post-infection. These studies will utilise Island's first manufactured batch of Galidesivir and will be conducted in a limited number of non-human primates. Data from these studies will be submitted to the FDA to support progression to the pivotal confirmatory phase.

In parallel, Island is finalising arrangements with Texas Biomedical Research Institute (Texas Biomed) a leading US BSL-4 facility, to undertake these studies. Discussions with additional partners are underway to further reduce development timelines. Texas Biomed scientists collaborate with industry and researchers globally and have helped deliver the first COVID-19 vaccine, the first Ebola treatment and first Hepatitis C

therapy.

Approval under the Animal Rule represents a transformational opportunity, providing a defined regulatory pathway for medical countermeasures targeting high-consequence viral threats. Animal Rule approval may unlock US Government procurement, including potential inclusion in the Strategic National Stockpile (SNS) – a pathway associated with significant, long-term, non-dilutive revenue.

In addition, approval would entitle Island to a Priority Review Voucher (PRV), a highly valuable regulatory incentive. The most recent PRV sale was US$200m, highlighting the substantial commercial potential associated with this program.

Collectively, the FDA's alignment and the defined two-stage pathway materially de-risk Galidesivir's development and create multiple avenues to unlock significant value.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"This is the clearest regulatory position we have received to date and it represents a major step forward for the Galidesivir program. The FDA has now confirmed the core elements of our animal model, including use of the Angola strain and has outlined the remaining requirements to progress through to approval via a defined, two-stage pathway under the Animal Rule. This level of clarity and alignment significantly de-risks the program."*

"We are now moving from regulatory definition into execution. The upcoming studies are tightly scoped, targeted and represent the final preparatory work before entering the pivotal confirmatory phase required for approval."

"Galidesivir aligns directly with US Government biodefence priorities. Approval under the Animal Rule may unlock Strategic National Stockpile procurement opportunities, while a PRV – most recently valued at US$200m represents a substantial non-dilutive value lever."

"With a clearly defined regulatory roadmap, strong FDA alignment and multiple sources of upside, Island has entered the pivotal phase in the evolution of the Galidesivir program. Our focus now is disciplined execution to unlock the full strategic and commercial potential of this asset."

Investor webinar:

The Company advises it will be hosting a webinar at 11:00am AEDT (8:00am AWST) on Thursday, 5 February 2026. During the webinar, CEO and Managing Director, Dr David Foster and Non-Executive Chairman, Mr Jason Carroll will provide an overview of the FDA's response and Galidesivir's imminent clinical development pathway.

The briefing will be followed by a Q&A session. Questions can be submitted to henry.jordan@sdir.com.au prior, or in written form during the webinar. Anyone wishing to attend the webinar must register via the following:

- https://us02web.zoom.us/webinar/register/WN_Zc-RdoU1S9mhpC8eyIjvOw

A recording of the presentation will be made available following the initiative.

Q&A:

What is the Animal Rule and how is it used as an approval pathway?

The Animal Rule is a specialised FDA approval pathway designed for situations where it is not ethical or feasible to run human efficacy trials — typically for high-consequence pathogens like Marburg, Ebola, anthrax, or smallpox.

Instead of proving efficacy in humans, the FDA allows approval based on:

- Well-controlled animal studies in a model that accurately reflects human disease
- Human safety data from Phase 1 studies
- PK/PD bridging, showing that the drug exposures that protect animals can be achieved safely in humans

The Animal Rule exists because outbreaks of these pathogens are rare, unpredictable, and often lethal, making traditional Phase 2/3 trials impossible.

What exactly did the FDA confirm, and why is it important?

The FDA confirmed the species, strain, and challenge dose — the three core pillars of the Animal Rule model. These are the hardest elements to secure and represent a major de-risking milestone. With these fundamentals aligned, the remaining steps are executional rather than conceptual.

What are the two stages of development the FDA has defined?

Stage 1 is dose-optimisation and PK/time-to-dose studies in a small number of non-human primates.

Stage 2 is the pivotal confirmatory study, which provides the primary efficacy evidence required for approval.

This two-stage sequence is now clearly defined and materially reduces regulatory uncertainty.

Why is the Angola strain being used and does Galidesivir work against it?

The Angola strain is the most clinically relevant Marburg variant, and it is the strain the FDA expects for approval. Galidesivir has demonstrated strong in vitro antiviral activity against both Angola and Musoke, supporting its use in the pivotal model.

Why would the FDA request a two-stage approach rather than one larger, multi-NHP study?

The FDA wants the pivotal study to be built on precise, data-driven parameters, not assumptions. A two-stage approach allows Island to first refine the dose, exposure and timing of treatment in a small, tightly scoped study before committing to the pivotal confirmatory phase.

This approach benefits everyone:

- It reduces the risk of a failed pivotal study. The FDA wants to ensure the dose, timing, and PK profile are correct before the confirmatory phase begins.
- It minimises animal use. The Animal Rule requires ethical, staged study design to avoid unnecessary NHP use.
- It avoids repeating a large, expensive study. A single large study without dose-optimisation carries a high risk of needing to be repeated — which the FDA wants to avoid.
- It accelerates the overall pathway. A small optimisation study is fast. Once the parameters are locked in, the pivotal study can proceed with confidence and fewer regulatory questions.

It aligns with how other successful Animal Rule programs have been previously run. At least six countermeasures approved under the Animal Rule used a staged program approach. This is believed to be standard from the FDA.

In short, the FDA is ensuring that the pivotal study — the one that determines approval — is designed correctly the first time, based on real data rather than assumptions. This materially de-risks the program and increases the probability of success.

What is the purpose of the dose-optimisation and PK studies?

These studies refine the minimum efficacious dose, confirm exposure levels, and determine the optimal treatment window post-infection. They are tightly scoped, short-duration studies that set up the pivotal confirmatory phase.

How soon can these studies begin?

Island has manufactured drug supply ready, and engagement with Texas Biomed (BSL-4) is advancing. These studies are positioned to commence in the near term, with additional partners being negotiated to accelerate timelines.

How does the Animal Rule pathway compare to traditional drug development?

It is significantly faster. There is no Phase 2 or Phase 3 human efficacy trial. Approval is based on animal efficacy and human safety. This dramatically shortens timelines and reduces development risk.

What is the commercial significance of a Priority Review Voucher (PRV)?

A PRV is a high-value, transferable asset. The most recent sale was US$200 million.
It represents a major source of non-dilutive value upon approval.

What is the Strategic National Stockpile (SNS) opportunity?

The SNS procures countermeasures for high-consequence pathogens. Inclusion can lead to multi-year, government-backed contracts with meaningful revenue potential. Galidesivir aligns directly with U.S. biodefence priorities.

What are the remaining risks, and how are they being managed?

The primary remaining risk is execution, not regulatory uncertainty.
Island has:

- A clearly defined FDA pathway
- Manufactured drug supply
- BSL-4 partners engaged
- A team with deep Animal Rule experience

These factors collectively reduce program risk and support a disciplined progression toward approval.

- Ends -

Approved for release to the ASX by:

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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.

About Texas Biomedical Research Institute

Texas Biomedical Research Institute (Texas Biomed) is a nonprofit research institute in San Antonio, Texas, dedicated to protecting the global community from infectious diseases. Through basic research, preclinical testing and innovative partnerships, the Institute accelerates diagnostics, therapies and vaccines for the world's deadliest pathogens. The highly secure and regulated 200-acre campus hosts the only private sector Biosafety Level 4 maximum-containment laboratory in the US, alongside a nationally designated primate research centre, providing unique infrastructure for infectious disease, biodefense, vaccine and antiviral research. Its work developing vaccines, therapies, and animal disease models, as well as its biosafety and regulatory expertise, have made it a trusted partner for governments, industry and academic collaborators.

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.