

31 August 2026

ASX Announcement

Pivotal Marburg data secured for Galidesivir FDA pathway

- **Signed Letter of Authorisation providing regulatory right to cross-reference detailed Marburg-Angola NHP natural history data in submissions to the US FDA**
- **Natural history data is an integral component of the FDA Animal Rule pathway and the evidence package required to support a potential New Drug Application**
- **Milestone directly addresses FDA feedback, where the regulator cited a full Marburg-Angola natural history study report was required to further assess Island's proposed NHP models**
- **Securing access avoids the need to independently recreate an equivalent Marburg natural history program, delivering savings in development time and capital as Island advances Galidesivir's clinical development**
- **Natural history data provides an important regulatory foundation for upcoming USAMRIID NHP dose optimisation study, expected to commence next quarter**
- **USAMRIID 20-NHP study will be complemented by planned 12-NHP Texas Biomed study, designed to evaluate Galidesivir following the onset of clinical signs and further characterise its potential therapeutic window**
- **Island now well placed to advance Galidesivir through pivotal animal studies towards a potential NDA submission and FDA approval**

MELBOURNE Australia, 31 August 2026: Australian antiviral drug development and biodefence company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to advise it has received a signed Letter of Authorisation ("LOA") providing the Company with the regulatory right to cross-reference a detailed non-human primate ("NHP") natural history study of Marburg-Angola virus in submissions to the US Food and Drug Administration ("FDA").

Receipt of the LOA represents an important regulatory milestone in Island's strategy to advance Galidesivir as a potential medical countermeasure for Marburg virus disease under the FDAs Animal Rule. It follows over six months of negotiations to secure access to the original and fully complete natural history study and directly addresses an information requirement identified by FDA through the Company's regulatory engagement.

The FDAs Animal Rule provides a pathway for the approval of medical countermeasures where human efficacy trials are unethical or infeasible. Under the pathway, efficacy can be established through adequate and well-controlled animal studies where the disease model is sufficiently characterised and the resulting data can support a reasonable prediction of clinical benefit in humans.

Natural history data are an integral part of this regulatory framework and the evidence package required to support a potential New Drug Application ("NDA"). These studies characterise the progression of disease in the absence of treatment, establishing the underlying disease model and baseline against which the efficacy of a therapeutic candidate can subsequently be assessed.



The importance of securing the detailed Marburg-Angola natural history dataset was specifically reinforced through Island's engagement with FDA. Following Type C meeting interactions regarding the Galidesivir development program, FDA advised that the published information available on the proposed NHP model was not sufficiently detailed for the regulator to determine whether the model was adequately characterised to support a potential Animal Rule filing. The FDA indicated that the full natural history study report was required to facilitate its further regulatory review.

Island subsequently commenced negotiations to secure the necessary regulatory access and has now obtained a signed LOA enabling the Company to cross-reference the detailed dataset in its FDA submissions.

Importantly, securing these rights allows Island to leverage an established and detailed body of Marburg focused natural history work rather than independently recreating an equivalent program. Marburg studies require highly specialised Biosafety Level 4 ("BSL-4") facilities, appropriate NHP models and extensive virological, clinical and pathological assessments. Replicating this work would require considerable additional time, capital and specialist resources.

The LOA therefore allows Island to direct its resources towards generating the Galidesivir-specific efficacy, dose-response, treatment-timing and pharmacokinetic data required to further advance the program, while providing an important regulatory foundation against which those results can be assessed.

Island is progressing a coordinated development strategy designed to build on the substantial body of existing Galidesivir data and generate the additional evidence required to support its potential development as a medical countermeasure for Marburg and other filoviruses.

The next component of this strategy is expected to be further evaluation of Galidesivir against Marburg virus under Island's existing Cooperative Research and Development Agreement ("CRADA") with the US Army Medical Research Institute of Infectious Diseases ("USAMRIID"). The USAMRIID program, commencing next quarter, is designed to assess Galidesivir in an NHP model following Marburg infection, including treatment at defined post-infection timepoints. This work is intended to provide additional efficacy data and further characterise the therapeutic window for Galidesivir.

The USAMRIID program will be complemented by Island's planned NHP efficacy study with Texas Biomedical Research Institute ("Texas Biomed") in Q1 CY27. The 12-NHP study has been designed to evaluate Galidesivir when treatment is initiated following the onset of clinical signs of infection, providing an important assessment of efficacy at a later and potentially more clinically relevant stage of disease.

Together, the USAMRIID and Texas Biomed programs are designed to assess Galidesivir across complementary treatment settings and progressively expand Galidesivir's efficacy dataset. The newly secured natural history study provides an important regulatory foundation for this work by establishing the underlying disease course against which treatment outcomes can be evaluated.

The studies form part of Island's broader strategy to systematically build the regulatory, efficacy and manufacturing package required to support a potential Galidesivir NDA under the Animal Rule, while also strengthening the program's relevance to US Government and other biodefence stakeholders.



Management commentary:

CEO and Managing Director, Dr David Foster said: *"Securing the right to cross-reference this natural history dataset is an important step in Galidesivir's development and directly addresses feedback from the FDA."*

"We've spent over six months working to secure access to this data. Importantly, it means we can leverage an established body of detailed Marburg-Angola natural history work rather than committing significant time and capital to recreating it ourselves, and instead direct those resources towards generating the Galidesivir-specific efficacy data required to advance the program."

"There is now a clear sequence of work ahead of us. Our upcoming USAMRIID program will provide further insight into Galidesivir's efficacy after Marburg infection, followed by the planned Texas Biomed study evaluating treatment after the onset of clinical signs. Together, these studies are designed to build a comprehensive efficacy dataset across different treatment windows."

"When combined with the significant body of existing Galidesivir data, over US\$70m of prior US Government investment and the manufacturing work we have underway, we are progressively assembling the regulatory, efficacy and manufacturing package required to advance Galidesivir under a potential FDA Animal Rule pathway."

"Marburg remains a significant global health and biodefence threat with no FDA-approved treatment and we believe Galidesivir is increasingly well positioned as a medical countermeasure."

- Ends -

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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.