4 December 2025

ASX Announcement

Additional FDA submission completed to optimise Galidesivir development program

- **Responses to previous guidance submitted to the FDA in accordance with stated time frame**
- **Follows FDA engagement which highlighted Galidesivir's applicability under the FDA's Animal Rule and Priority Review voucher eligibility**
- **Pending FDA response expected to provide further insight on Galidesivir's development program under the Animal Rule**
- **FDA response anticipated prior to 2 January 2026 (US time)**
- **Latest round of clarifications forms part of ongoing and comprehensive FDA engagement process ahead of Galidesivir development program**

MELBOURNE Australia, 4 December 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to confirm it has submitted its responses to previous guidance provided by the US Food & Drug Administration (FDA) on the clinical development program for Galidesivir.

It follows recent confirmation by the FDA that developing a countermeasure for Marburg virus is eligible for the Animal Rule pathway – a significant regulatory derisking event which positions the Company to advance to the next stage of development for the Galidesivir program (*refer ASX Announcement 17 November 2025*).

Along with confirmation of the Animal Rule pathway, the FDA also provided valuable guidance on Galidesivir's development program to advance approval under the Animal Rule.

The Company was then given the opportunity to submit questions to the FDA by 2 December 2025 (US time), which it has now completed in accordance with the designated time frame.

The submission by Island comprises written responses and requests for clarifications where applicable, and marks an important step in ILA's ongoing and comprehensive engagement with the FDA to optimise its development program design in accordance with the highest standards of safety and quality control. A response from the FDA is anticipated by 2 January 2026 (US time).

The Company will incorporate all additional guidance into its NHP study design that will be finalised in close consultation with the FDA. Island is currently advancing agreements with potential facilities to conduct the agreed upon study and continuing US Government engagement initiatives.

The Company intends to commence the Marburg study in Q1 CY26 based on program approval by FDA.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"We are pleased to complete these questions and clarifications and submit them to FDA. This marks the next step in our comprehensive regulatory engagement strategy and is based on the detailed advice on program design already provided by the FDA. We look forward to working closely with the FDA to finalise the development program design as we pursue a direct pathway to market for the Galidesivir program."*

- 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.

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.