

**1 September 2025**

ASX Announcement

## **FDA meeting request lodged for Galidesivir**

- **Type C meeting request submitted to Food and Drug Administration on 29 August 2025 (US time)**
- **Island to seek alignment with FDA on utilising Animal Rule to fast-track Galidesivir approval for use in Marburg**
- **Meeting with FDA expected to occur next quarter, in line with stated timeframes**
- **Additional work to advance animal study using Galidesivir in Marburg is well advanced – Study remains on track to commence and complete next quarter**

**MELBOURNE Australia, 1 September 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to advise it has formally lodged a request for a Type C meeting for Galidesivir with the US Food and Drug Administration (FDA) as part of the Company's open Investigational New Drug (IND) application. The request was lodged with the regulator on Friday, 29 August 2025 (US time).

The meeting request formally initiates communication with the FDA regarding the development of Galidesivir for the treatment of Marburg. The aim of the meeting is to seek alignment with the regulator regarding the use of the Animal Rule for Galidesivir's development and potential approval. The meeting will also serve to provide feedback on any other required documentation, study design, quality control and Priority Review Voucher (PRV) potential.

The FDA's Animal Rule allows for a drug approval in indications based on animal efficacy data, when human trials are unethical or not feasible, provided safety is shown in humans and the disease is well modelled in animals. Based on previous clinical development work, which was underpinned by over US\$70m in funding support from the US government, Island may have the opportunity to undertake only one additional animal efficacy study, prior to the submission of a New Drug Application (based on successful results).

Lodgement of the request is in line with the Company's stated timeframe for the ongoing development of Galidesivir. Island has requested an in person meeting with the regulator in Q4 CY25. Concurrently, the Company is advancing engagement with sites and counterparties for pending studies using Galidesivir in Marburg, which will include an animal study in the next quarter.

### **Management commentary:**

**CEO and Managing Director, Dr David Foster said:** *"We are very pleased to have commenced engagement with FDA around the development and approval strategy for Galidesivir. This meeting will provide the opportunity to gain important feedback from the regulator and seek alignment on use of the Animal Rule to accelerate the approval process."*

*"Alongside this, we are continuing to work with a number of sites and potential partners to identify an appropriate facility for the planned animal study."*



*“This work is well progressed and will be a critical step in the development of Galidesivir, ahead of advancing our stated strategy to become a trusted provider to government stockpiles, by supplying solutions for high-priority public health threats like Marburg.”*

**- Ends -**

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**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, Automatic Registry Services, whose contact info is housed on the Shareholder Services page of the Company’s website.*

Visit [www.islandpharmaceuticals.com](http://www.islandpharmaceuticals.com) for more on Island.