19 September 2025

ASX Announcement

US Food & Drug Administration meeting request granted

- **FDA grants Island a Type C meeting under Galidesivir's open Investigational New Drug (IND) application**
- **Provides ILA with the opportunity to seek alignment on utilising Animal Rule to fast-track Galidesivir approval for use in Marburg**
- **Additional feedback to provide clarity on pending animal study design and Priority Review voucher eligibility**
- **Written responses from the FDA expected by 12 November 2025 (US time)**
- **Island to submit comprehensive briefing package with relevant historical data to regulator in the coming weeks**

MELBOURNE Australia, 19 September 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to advise that the US Food & Drug Administration (FDA) has granted the Company's Type C meeting request as part of Galidesivir's open Investigational New Drug (IND) application (refer ASX announcement: 1 September 2025).

This meeting provides the Company with the opportunity to seek alignment with the regulator on the use of the FDA's Animal Rule for Galidesivir's development and approval. Island will also request guidance on its proposed clinical study design, and Galidesivir's eligibility for a Priority Review Voucher (PRV).

The FDA has determined that written feedback will be the most appropriate means for responding to this meeting request and has indicated that it intends to provide this to the Company by 12 November 2025 (US time). Prior to receipt of responses, Island will submit a full briefing package, which includes all relevant historical Galidesivir data.

Concurrently, Island is continuing to advance negotiations with strategic counterparties to progress an animal study using Galidesivir in Marburg. This study remains on track to commence and complete in the next quarter.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"Securing this Type C meeting with the FDA represents an important milestone in advancing Galidesivir towards approval. The guidance from the regulator is expected to provide clarity on the potential to leverage the Animal Rule, as well as important insight into study design requirements and Galidesivir's eligibility for a PRV. This meeting will be supported by a comprehensive briefing document, scheduled to be sent to the regulator in the coming weeks."*

"We look forward to receiving feedback in the coming months, as we continue to advance additional opportunities to underpin our stated strategy of becoming a trusted provider to government stockpiles, by supplying solutions for high-priority public health threats like Marburg."

- 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.