**29 September 2025**

ASX Announcement

# US Food & Drug Administration Type C meeting briefing document submitted

- **FDA type C meeting provides opportunity to seek alignment on Animal Rule use to fast-track Galidesivir approval in Marburg**
- **Pending responses to also clarify planned study design and confirm Priority Review Voucher potential**
- **Robust briefing package includes pharmacokinetic, safety and animal study results, as well as supporting documentation around use of Animal Rule**
- **Dossier submitted to provide full context to FDA ahead of written responses – expected 12 November 2025 (US time)**
- **Negotiations with potential strategic counterparties to advance planned animal study in Marburg reaching final stages**

**MELBOURNE Australia, 29 September 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to advise it has completed the submission of all briefing documentation to the US Food & Drug Administration (FDA), in relation to the Company's Type C meeting to advance Galidesivir's approval pathway (refer ASX announcement: 19 September 2025).

The Company's meeting with the FDA provides an opportunity to seek alignment with the regulator on the use of the FDA's Animal Rule for the clinical development and approval of Galidesivir. The FDA indicated its goal of providing written responses to the Company to clarify its requests by 12 November 2025.

The documentation submitted to the FDA in support of its engagement includes relevant background on Galidesivir's historical clinical development, pharmacokinetic and safety data, non-human primate study results and supporting documentation regarding the use of the Animal Rule for approval.

Prior to the response from the FDA, Island intends to finalise negotiations with a strategic counterparty to advance its proposed animal study in Marburg. This will allow the Company to complete the initiative in line with its stated timeframe of Q4 CY25.

**Management commentary:**

**CEO and Managing Director, Dr David Foster said**: *"The completion of our Type C meeting submission marks another important step forward in progressing Galidesivir's regulatory pathway with the FDA. By providing a robust and comprehensive package, that captures the breadth of historical clinical data, pharmacokinetics, safety outcomes and exceptional non-human primate study results, we have ensured the FDA has the full context to assess our queries and provide a guide on NDA approval for Galidesivir. We look forward to receiving the FDA's written feedback in November, which will guide our next steps, including an indication on how to best design and undertake the planned Marburg animal study."*

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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, 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.