22 October 2025

ASX Announcement

US Food & Drug Administration confirms response timing for Galidesivir clinical development and approval

- **FDA confirms that responses remain on schedule for 12 November 2025 (US time), despite US Government shutdowns**
- **Responses from regulator expected to provide 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**
- **Follows submission of a robust briefing package which includes pharmacokinetic, safety and animal study results, as well as supporting documentation around use of Animal Rule**
- **Negotiations with strategic counterparties to advance planned animal study in Marburg reaching final stages**

MELBOURNE Australia, 22 October 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to advise it has received further correspondence from the US Food & Drug Administration (FDA), in relation to the Company's Type C meeting to advance Galidesivir's approval pathway.

The correspondence confirms the FDA's goal to provide written feedback to the Company by 12 November 2025 (US time). This is a pleasing development, given the operational disruption following the recent US Government shutdown.

The additional correspondence follows grant of a Type C meeting request (refer ASX announcement: 19 September 2025), which provides Island with the opportunity to seek alignment with the FDA on the use of the FDA's Animal Rule for Galidesivir's development and approval. The Company has also requested guidance on the proposed study design for its upcoming non-human primate study using Galidesivir in Marburg and Galidesivir's eligibility for a Priority Review Voucher (PRV).

To support the FDA's pending written responses, Island has submitted all relevant briefing documentation to the regulator which encapsulates 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 (refer ASX announcement: 29 September 2025).

Concurrently, the Company continues to advance negotiations with strategic counterparties for its proposed animal study in Marburg.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"Receiving confirmation from the FDA that written feedback remains on schedule – despite the backdrop of US government shutdowns – is a very positive development for Island and highlights Galidesivir's potential public health importance."*

"Maintaining this level of engagement with the FDA during a period of widespread operational disruption reflects the strength of our communication with the Agency and the seriousness with which Galidesivir's development and potential approval pathway is being treated."

"We look forward to receiving the FDA's formal written guidance next month as we continue to progress both regulatory and operational milestones in parallel."

- 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.