5 January 2026

ASX Announcement

Ongoing engagement with the US FDA to advance Galidesivir's clinical development

- **FDA confirms it is progressing its review of Island's recent submission regarding clarifications Galidesivir's clinical development**
- **Follows previous guidance from the FDA confirming Animal Rule and Priority Review Voucher eligibility**
- **Island confirms no adverse feedback or additional data requests were received from FDA in most recent correspondence**
- **Engagement with regulator continuing in relation to receipt of responses, which will provide important feedback on pending clinical trial initiatives in Marburg**
- **Study preparation, US government engagement and negotiations with potential study partners continuing in parallel**

MELBOURNE Australia, 5 January 2026: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) wishes to provide the following update on its ongoing correspondence with the with the US Food & Drug Administration (FDA) in relation to Galidesivir's clinical development.

Island received correspondence from the FDA on 2 January 2026 (US time) advising that the regulator requires additional time to finalise its response to the Company's recent submission, which sought further clarification on Galidesivir's development pathway under the FDA's Animal Rule (refer ASX announcement: 4 December 2025). This followed confirmation of Galidesivir's eligibility for approval under the Animal Rule pathway and Priority Review Voucher status – a major milestone for the Company.

The Company notes that the FDA has not provided any adverse commentary, requested additional information, or altered its previously communicated regulatory position. Island remains in constructive dialogue with the FDA and will update the market as further guidance is received.

Island continues to progress preparatory activities in parallel, including advancing discussions with facilities to conduct the planned non-human primate study and maintaining active engagement with US Government stakeholders. The Company remains positioned to incorporate FDA guidance promptly upon receipt and progress toward study initiation, subject to FDA program approval.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"While we had hoped to receive FDA feedback by this date, we see the additional review time as a constructive step in what has been a highly collaborative regulatory process to date. In management's view, the additional time being taken reflects the importance of the guidance being contemplated under the Animal Rule pathway and the seriousness of which the FDA is considering Galidesivir's next phase of clinical development.*

"While we await clarifications around the proposed timeframe for the FDA's response, we continue to advance all parallel preparatory work and remain focused on moving efficiently into the next phase of Galidesivir's development, once feedback is received."

- 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.