17 June 2026

ASX Announcement

Galidesivir granted Orphan Drug Designation by US Food & Drug Administration for Marburg

- **US FDA grants Orphan Drug Designation to Galidesivir for post-exposure prophylaxis of Marburg virus disease**
- **Designation further strengthens the regulatory and commercial position of the Galidesivir program prior to dose optimisation initiatives next quarter**
- **Orphan Drug Designation provides access to potential benefits including seven years of market exclusivity in the US upon approval**
- **Designation also provides exemption from certain FDA fees and regulatory support throughout development**
- **Reinforces the potential breadth of Galidesivir's application as a medical and biodefence countermeasure for high-consequence viral threats**
- **Follows recent, strong progress across manufacturing, regulatory and study activities supporting advancement under the FDA Animal Rule pathway**
- **Continues growing regulatory momentum as Island advances Galidesivir towards potential approval and commercialisation**

MELBOURNE Australia, 17 June 2026: Australian antiviral drug development and biodefence company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to advise that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation to Galidesivir for the post-exposure prophylaxis (PEP) of Marburg virus disease.

The designation represents an important regulatory milestone for the Galidesivir program and further strengthens its long-term strategic positioning as Island advances development of the asset under the FDA Animal Rule pathway.

Orphan Drug Designation is intended to encourage the development of therapies for rare diseases and conditions and provides a range of potential regulatory and commercial benefits, including eligibility for seven years of market exclusivity in the United States following approval for the designated indication, exemption from certain FDA application fees and access to regulatory assistance throughout development.

The designation further expands the regulatory foundations supporting the Galidesivir program and highlights the potential versatility of the asset across a range of biodefence and outbreak preparedness applications.

The milestone follows a period of significant progress for the Galidesivir program. In recent months, Island has executed an expanded Cooperative Research and Development Agreement (CRADA) with the US Army Medical Research Institute of Infectious Diseases (USAMRIID), secured supply of non-human primates required for the planned dose optimisation study, commenced GMP manufacturing activities and continued preparations for pivotal studies required to support potential approval under the FDA Animal Rule pathway.

Collectively, these initiatives continue to strengthen the clinical, regulatory and manufacturing foundations of the program while positioning Galidesivir for the next phase of development, which will commence with dose optimisation initiatives next quarter.

Management Commentary:

Chief Executive Officer and Managing Director, Dr David Foster, said: *"The granting of Orphan Drug Designation represents another important regulatory milestone for the Galidesivir program and further strengthens the strategic position of the asset as we continue to advance towards dose optimisation next quarter, prior to potential pivotal studies and an approval in the US.*

"In addition to the regulatory benefits associated with orphan designation, this outcome expands the opportunities available to the program and reinforces the potential breadth of Galidesivir's application as a medical and biodefence countermeasure.

"Importantly, this designation builds on the considerable progress we have made across regulatory, manufacturing and development activities since acquiring the asset eleven months ago. Together, these achievements continue to de-risk the program and strengthen the foundations required to maximise the long-term value of Galidesivir."

- Ends -

Approved for release to the ASX by:

David Foster (CEO and Managing Director)
Island Pharmaceuticals Limited
info@islandpharmaceuticals.com

Investors and media, for further information, please contact:

Henry Jordan
Six Degrees Investor Relations
+61 (0) 431 271 538
henry.jordan@sdir.com.au

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.