

7 July 2026

ASX Announcement

## **Government approvals secured for the use of Galidesivir as a treatment for Bundibugyo Ebola epidemic in Africa**

- All government and regulatory approvals obtained for the compassionate use of Galidesivir as a treatment for infected patients during the ongoing Bundibugyo Ebola epidemic in Uganda
- Island to utilise opportunity to generate human data in an active outbreak setting under the World Health Organization's (WHO) internationally recognised emergency clinical framework as part of development
- Marks a major opportunity to generate prospective human efficacy, safety and virological data during an active Ebola outbreak – Galidesivir to be deployed within CY26
- Positions Galidesivir as a potential treatment for Bundibugyo Ebola virus disease, where patients currently have no approved therapeutic options
- Bundibugyo Ebola epidemic continues to escalate, with 1,480+ confirmed cases, ~450 deaths across multiple densely populated African countries
- Concurrent Ebola and Marburg virus activity in Uganda highlights the growing importance of broad-spectrum antiviral therapies and medical countermeasures such as Galidesivir
- Sponsored by the Uganda Ministry of Health and supported by the World Health Organization (WHO) and leading African infectious disease institutions, validating Galidesivir's potential as a treatment for Ebola
- Program fully funded by government and supporting institutions, with Island's contribution limited to the supply of Galidesivir, providing a highly capital-efficient and non-dilutive clinical development opportunity
- Government-sponsored opportunity follows rigorous regulatory and ethics review involving Uganda's public health, scientific and regulatory authorities
- Clinical opportunity complements demonstrated efficacy in non-human primate (NHP) filovirus models and Island's FDA Animal Rule approval strategy
- Opportunity advances Galidesivir across two potential complementary development pathways, combining prospective human Ebola clinical data with ongoing pivotal Marburg efficacy studies under the FDA Animal Rule
- Previous NHP studies demonstrated 100% survival in Galidesivir-treated Ebola Zaire-infected primates compared with 0% survival in placebo-treated controls
- Drug deployment to be enabled by recently executed GMP manufacturing campaign, demonstrating readiness to address emerging global viral outbreaks
- Effort further advances Galidesivir towards potential government procurement, biodefence stockpiling and broader commercialisation opportunities as a broad-spectrum antiviral
- Investor webinar to be held on Wednesday, 8 July CY26 at 11:00am AEST

**MELBOURNE Australia, 6 July 2026:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to advise that



is has secured all regulatory and ethics approvals to enable the compassionate use treatment of patients infected during the current Bundibugyo Ebola virus outbreak in Uganda using Galidesivir under a Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) protocol.

The current Bundibugyo Ebola epidemic continues to accelerate across multiple African countries including the Democratic Republic of Congo and Uganda. As of 6 July 2026, there are 1,481 confirmed cases, 454 deaths and a rising case fatality rate of 31%. Upwards of 70 new cases are being reported daily, leading to a broader spread into multiple new provinces.

Emergency public-health measures have now been implemented in Kinshasa, the most densely populated city in the DRC, the third-most populous city and third-largest metropolitan area in Africa, which has a population of over 15m people. Separately, Uganda, which shares a border with the DRC has also confirmed a Marburg virus fatality, marking a rare dual-pathogen event.

Under the approved program, eligible patients will receive Galidesivir during the current and subsequent outbreaks, with investigators prospectively collecting clinical, safety and virological data in accordance with the World Health Organization (WHO) recognised Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) framework.

The study has been specifically established to provide compassionate use of investigational therapies during public health emergencies where no approved treatment options exist and conventional randomised clinical trials cannot be ethically implemented.

There are currently no approved therapeutics or vaccines for Bundibugyo Ebola or Marburg virus, creating an urgent unmet medical need and a unique opportunity for Galidesivir to be evaluated in the intended disease setting while providing a new treatment option currently unavailable anywhere for Ebola patients.

The study will be conducted in collaboration with the ACCEPT-Africa Consortium, the Infectious Diseases Institute (IDI) at Makerere University and the Uganda Ministry of Health following receipt of approvals from the relevant Research Ethics Committee, Uganda's National Drug Authority (NDA) and the Uganda National Council for Science and Technology (UNCST).

The approvals represent the culmination of over 12 months of collaboration between Island and ACCEPT-Africa, which commenced with the objective of establishing clinical capability and outbreak preparedness to evaluate Galidesivir in Africa. Following the emergence of the current Bundibugyo Ebola outbreak, the collaboration transitioned from preparedness planning to implementation of the approved MEURI protocol, enabling rapid deployment of Galidesivir while prospectively collecting valuable clinical data.

Island is now working alongside its established partner network to rapidly supply GMP-grade Galidesivir to participating treatment sites, leveraging the Company's GMP manufacturing program (refer ASX announcement: 4 June 2026) to support patient treatment under the approved protocol. Island is also operationalising an additional acceleration pathway that may allow Galidesivir to be available for compassionate use prior to the end of CY26.

### **Opportunity overview:**



The effort will utilise the WHO's MEURI framework, an internationally recognised mechanism established following the 2014 West African Ebola outbreak to facilitate access to promising investigational therapies during public health emergencies where no approved treatment options exist and conventional randomised clinical trials cannot be implemented. The framework was subsequently adopted extensively during the COVID-19 pandemic and provides a structured pathway between traditional compassionate use and formal clinical trials.

Unlike conventional compassionate use programs, the MEURI framework requires prospective collection of clinical, safety and virological data under an approved protocol, enabling investigators to systematically evaluate patient outcomes while providing access to potentially beneficial investigational therapies. The protocol incorporates predefined clinical assessments, safety monitoring and outcome measures, creating an important source of real-world evidence from patients treated during an active outbreak.

Approval to administer Galidesivir under the MEURI framework was granted after satisfying stringent ethical and scientific requirements, including the absence of satisfactory approved treatment alternatives, supporting preclinical and clinical evidence for Galidesivir, confirmation that a conventional randomised clinical trial was not immediately feasible during the outbreak, informed patient consent and approvals from Uganda's relevant ethics and regulatory authorities.

### **Strategic significance:**

The study represents the first opportunity for Galidesivir to be prospectively evaluated in patients during an active Ebola outbreak and marks an important expansion of the Company's clinical development strategy.

Galidesivir is now advancing through two potential complementary US Food and Drug Administration (FDA) aligned pathways. Real-world clinical deployment under MEURI and controlled NHP efficacy studies under the FDA Animal Rule. Very few antiviral programs globally have ever had both pathways open simultaneously.

While Island's primary regulatory pathway for Galidesivir remains progression under the FDA's Animal Rule, the MEURI study provides a complementary opportunity to generate prospective human clinical, safety and virological data in the intended disease setting while simultaneously providing a novel treatment option to Ebola-infected patients in Africa.

Data generated through the study may provide supportive evidence alongside previously undertaken controlled NHP efficacy studies and broader regulatory package.

The regulatory architecture mirrors the pathway used by the only two FDA-approved Ebola therapeutics, Ebanga and Inmazeb, which achieved approval based on moderate efficacy supported by real-world outbreak data. Since approval, these products have generated more than US\$1Bn in government procurement and Strategic National Stockpile orders.

The effort also demonstrates the strategic value of Island's recent investment in GMP manufacturing, enabling rapid deployment of clinical-grade Galidesivir in response to an emerging outbreak. In addition, the program strengthens the Company's relationships with leading African infectious disease researchers and public health agencies, positioning Island to participate in future outbreak response initiatives involving Ebola and other high-consequence viral threats.



Importantly, the MEURI program is sponsored by the Government of Uganda and funded through various institutions, making this a non-dilutive clinical development opportunity for Island shareholders.

Galidesivir's broad-spectrum antiviral profile, with cell culture or NHP efficacy data across Ebola, Marburg and Sudan viruses, positions it uniquely for multi-filovirus outbreaks where species identification may be delayed or co-circulation occurs.

### **Management commentary:**

**Chief Executive Officer and Managing Director, Dr David Foster, said:** *"Securing all regulatory and ethics approvals to commence this effort represents a significant milestone for Galidesivir and the culmination of more than a year of collaboration with our partners in Uganda and the ACCEPT-Africa Consortium. The decision to approve this program reflects a rigorous scientific and ethical review process involving Uganda's leading regulatory and public health authorities and provides an important validation of Galidesivir's existing body of preclinical and clinical evidence.*

*The current Bundibugyo Ebola outbreak highlights the urgent need for new antiviral treatment options. With no approved therapeutics for Bundibugyo Ebola or Marburg virus, and with the outbreak accelerating across multiple provinces, the WHO's MEURI study framework provides the first opportunity to evaluate Galidesivir in real-world infected patients while prospectively collecting clinical, safety and virological data.*

*Together with our ongoing FDA Animal Rule program and previously generated efficacy data in non-human primate filovirus models, this study represents a rare dual-pathway opportunity to advance Galidesivir toward potential approval and future government procurement."*

### **Investor webinar:**

Island will host an investor webinar at 11:00am AEST (9:00am AWST) on Wednesday, 8 July CY26. During the webinar, CEO and Managing Director, Dr David Foster and Non-Executive Chairman, Mr Jason Carroll will provide a broader insight into the in-human trial in Africa and provide an update on its broader biodefence engagement and other near-term opportunities.

- [https://us02web.zoom.us/webinar/register/WN\\_EWOnWnlaRoiPAChkkaBV8A](https://us02web.zoom.us/webinar/register/WN_EWOnWnlaRoiPAChkkaBV8A)
- Date and time: 11:00am AEST (9:00am AWST) on Wednesday, 8 July CY26

### **About ACCEPT-Africa:**

The ACCEPT-Africa Consortium is a multinational infectious disease research network comprising leading clinical, academic and public health institutions across Africa and Europe focused on preparedness and rapid response to emerging viral outbreaks.

Island's collaboration provides access to an established network of experienced outbreak investigators, treatment centres and public health agencies capable of rapidly initiating clinical programs during future Ebola and other filovirus outbreaks. Beyond the current study, the relationship enhances the Company's ability to evaluate Galidesivir in outbreak settings and supports its long-term strategy of developing the asset as a broad-spectrum antiviral and biodefence countermeasure.

## Q&A

### **What are filoviruses and why are they so deadly?**

Filoviruses are a family of single-stranded, negative-sense RNA viruses that cause severe viral haemorrhagic fever, including Ebola virus disease (EVD), Bundibugyo virus disease (BVD), Sudan virus disease (SVD) and Marburg virus disease (MVD).

They are deadly because they replicate extremely rapidly, trigger massive immune dysregulation, cause vascular leakage, multi-organ failure, and often death. Case fatality rates range from 30% to 88%, depending on the species and outbreak conditions.

### **How are filoviruses transmitted?**

Transmission occurs through direct contact with infected bodily fluids (blood, vomit, stool, sweat, saliva), contaminated surfaces, or via unsafe burial practices. High viral loads in late-stage disease make transmission particularly efficient.

### **What is Bundibugyo Ebola virus (BDBV) and how does it differ from Ebola Zaire?**

BDBV is a genetically distinct Ebola species with historically high case fatality rates (25–36%). Unlike Ebola Zaire, there is no approved vaccine and no approved therapeutic for Bundibugyo Ebola. The extended time an infected patient can mingle within a population before presenting with the significant illness enables the virus more time to infect others. This makes the current outbreak significantly more dangerous than Ebola Zaire.

### **Is it true that Marburg virus been identified within the Ebola outbreak area and what does this mean for Galidesivir?**

Yes, Marburg virus has been identified in Uganda with at least one confirmed death of a one-year-old child that we know of to date (but anecdotal reports suggest others have been detected).

Dual-pathogen (BDBV + MARV) co-circulation is extremely rare and operationally complex. You have two of the world's most deadly viruses circulating within a single outbreak – this highlights the need for broad-acting antivirals capable of treating multiple filoviruses especially when the delay in confirming an infected patient's virus takes up to 24 hours in some parts of Africa.

Galidesivir is one of the few candidates with cross-species activity and with strong NHP treatment efficacy data in treating both Marburg and Ebola infections.

### **What is Marburg virus and why is it a priority pathogen?**

Marburg virus is a filovirus with case fatality rates historically reaching 88%. There are no approved antivirals or vaccines, and outbreaks are often explosive. The confirmed Marburg death in Uganda during the current Ebola outbreak represents a rare dual-pathogen event.

### **How large is the current outbreak?**



Recent reports show 1,481 cumulative confirmed cases, increasing at over 70 cases per day as well as 454 deaths, with a rising case fatality rate of 31%. The outbreak has expanded into multiple new provinces and triggered emergency measures in Kinshasa (a high-density city with over 15 million inhabitants). This has the potential to take two deadly viral diseases that are usually confined to small villages and localised areas, into completely new territory.

### **Why is the outbreak escalating so quickly?**

Factors include a longer time to show significant symptoms allowing infected individuals to pass the virus to others, inconsistent testing, poor infrastructure and allowing the virus to spread into densely populated regions. Kinshasa's involvement (15+ million people) has the potential to lead to a major escalation.

### **What is the MEURI framework and why is it important?**

MEURI (Monitored Emergency Use of Unregistered and Investigational Interventions) is a WHO-endorsed framework allowing emergency access to investigational therapeutics during outbreaks. Uganda's MEURI platform is one of the most advanced globally and is fully approved through 2031 (UNCST HS7969ES).

### **What does Galidesivir's inclusion in the MEURI protocol mean?**

The inclusion in the MEURI protocol means that Galidesivir will be authorised for emergency therapeutic use in patients infected with:

- Bundibugyo virus (BDBV)
- Ebola virus (EBOV)
- Sudan virus (SUDV)
- Marburg virus (MARV)
- Tai Forest virus (TAFV)

The protocol identifies Galidesivir as a broad-spectrum RNA polymerase inhibitor with activity across multiple filoviruses, supported by non-human primate data.

### **Is Island paying for the MEURI study?**

No. The MEURI program is a fully funded, compassionate use program, sponsored by the Government of Uganda and supported by a number of core donors. Island's responsibility is limited to supplying Galidesivir. This makes the study non-dilutive for shareholders.

### **Why is real-world outbreak data so valuable for FDA approval?**

In 2018-19, two Ebola Zaire therapeutics achieved FDA approval in 2020 based on moderate efficacy combined with real-world outbreak data. Both products remain in the U.S. Strategic National Stockpile. Galidesivir now has the same opportunity.

### **What are the two distinct FDA pathways now available to Galidesivir?**

**Pathway 1:** Real-world clinical data from MEURI use in Bundibugyo Ebola patients.

**Pathway 2:** Controlled non-human primate efficacy data from the ongoing USAMRIID Marburg challenge study. Together, these form a dual-track regulatory strategy.



## **What makes Galidesivir a strong antiviral candidate?**

Galidesivir is a nucleoside analogue that inhibits viral RNA polymerase. It has demonstrated activity across Ebola, Marburg, Sudan virus and other filoviruses in preclinical studies, including non-human primates.

## **How does Galidesivir compare to monoclonal antibodies?**

Monoclonal antibodies are strain-specific and require precise matching. Galidesivir is **strain-agnostic**, making it ideal for multi-filovirus outbreaks or situations where species identification is delayed.

## **How will data be collected under the MEURI program?**

Clinicians will collect clinical, virologic, safety, and operational data under national oversight. This includes PCR results, symptom progression, supportive care measures, and outcomes.

## **How soon could Galidesivir generate meaningful clinical data?**

Outbreak velocity is high (70+ new cases each day which is expected to accelerate). MEURI deployment can begin immediately upon drug arrival, meaning data could begin accumulating rapidly.

## **Does Galidesivir have safety data in humans?**

Yes. Galidesivir has been administered in human studies and has a safety profile informed by prior clinical trials and extensive preclinical work.

## **What is the commercial opportunity if Galidesivir succeeds?**

Filovirus countermeasures are procured by national governments, WHO, Africa CDC, BARDA, and the U.S. Strategic National Stockpile. These are large, recurring, government-funded markets. Ebanga was used in a similar way during the 2018-19 Ebola Zaire outbreak – after showing a 14% improvement in survival rate in patients (vs standard of care), that was deemed sufficient to receive an FDA approval in 2020 and, since that time, Ebanga has secured SNS orders of over US\$700M since approval.

## **Could Galidesivir be stockpiled internationally?**

Yes. If efficacy is demonstrated and regulatory approval is achieved, Galidesivir could be procured for national stockpiles, like existing Ebola therapeutics.

## **Why is this moment transformational for Island Pharmaceuticals?**

Galidesivir is now entering real-world clinical use in an escalating outbreak with no approved therapeutics against Bundibugyo Ebola, while simultaneously advancing through a controlled Marburg NHP study. This dual-pathway opportunity is exceptionally rare and positions Island for potential accelerated regulatory progression.

**- Ends -**

**Approved for release to the ASX by the Board.**



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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, Automatic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.*

Visit [www.islandpharmaceuticals.com](http://www.islandpharmaceuticals.com) for more on Island.