
# COMBATTING URGENT VIRAL DISEASE THREATS

## DR DAVID FOSTER, MANAGING DIRECTOR

8 October 2024

(ASX: ILA)

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# Island Pharmaceuticals (ASX:ILA) is an antiviral therapeutics company targeting infectious diseases


ASSETS:

- Known small molecules with clinical history
- Mid/late stage clinical or other abbreviated routes
- Open USFDA INDs
- Validated US Govt/military funding support
- Priority Review Voucher eligible

RAPID PATHS TO MARKET

# ISLAND AT A GLANCE

## Dengue infects up to 400m per year*

Now **endemic in more than 100 countries** with no current pharmaceutical treatment.

## Major market potential

ISLA-101 has potential to address mosquito-borne diseases, which are being driven by **climate change.**

## Positive results in aggressive models

In **animal and human cellular models** of dengue and Zika infections + other flavivirus data.

## Phase 2 PROTECT clinical trial in dengue underway

Subjects in **Phase 2a prophylactic arm dosed** and data expected by end 2024

## Priority Review Voucher potential

For ISLA-101 at the time of FDA approval. Last ten PRVs sold for an average of **US~$110M.**

## Pipeline expansion

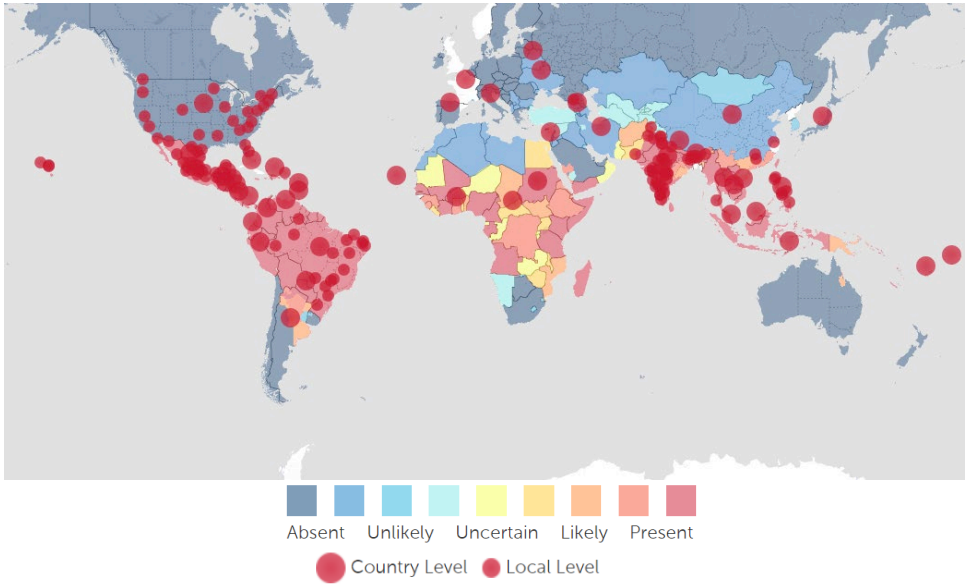
Executed Letter of Intent for potential **acquisition of antiviral molecule, Galidesivir .**

**WHO, 17 March 2023.*

# DENGUE IS A WIDESPREAD ISSUE

## Dengue outbreaks occurred in many countries of the world in the Americas, Africa, the Middle East, Asia, and the Pacific Islands

*HealthMap: recent reports of local or imported dengue cases*




https://www.healthmap.org/dengue/en - visited September 26,, 2024

Sri Lankan authorities rush to contain dengue fever outbreak

Vietnam's dengue fever cases nearly top 100,000

Bangladesh reports 509 dengue hospitalisations, two deaths in a day

Singapore on alert for fresh dengue fever outbreak

Malaysia dengue cases top 54K, Up 150% from last year - Outbreak News Today

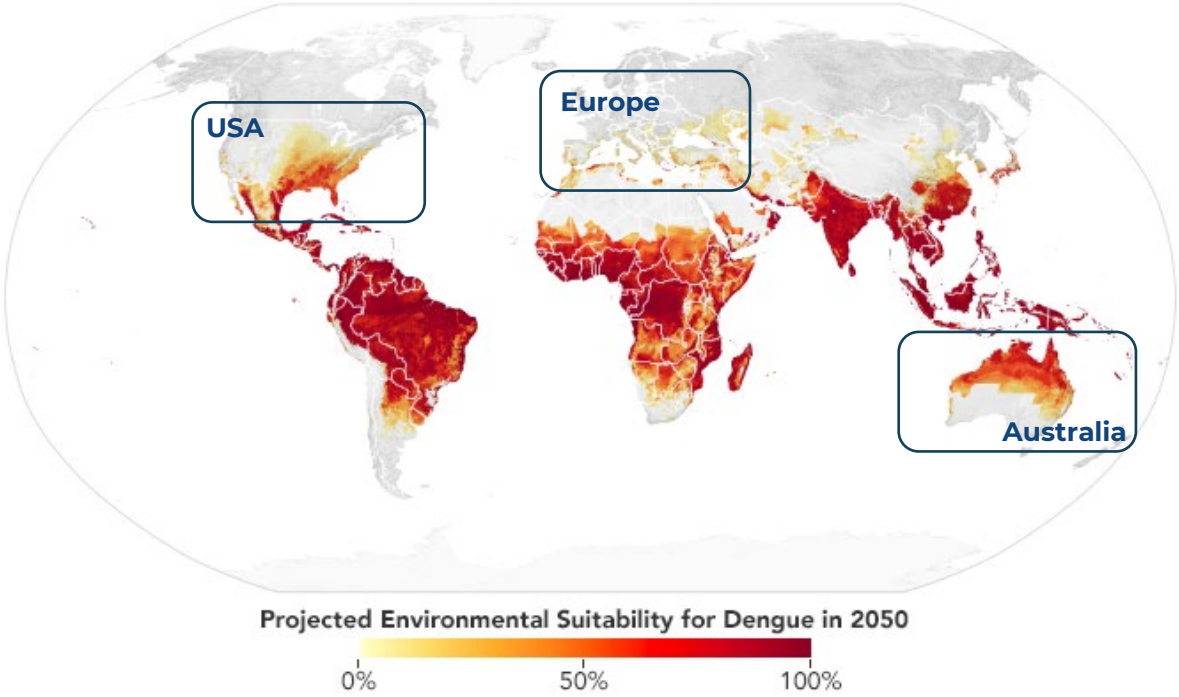
Peru declares national emergency as dengue outbreak kills 200 and swamps hospitals

Dengue cases reach 647 in Barbados

Global dengue surge sparks concern as cases top 5 million this year

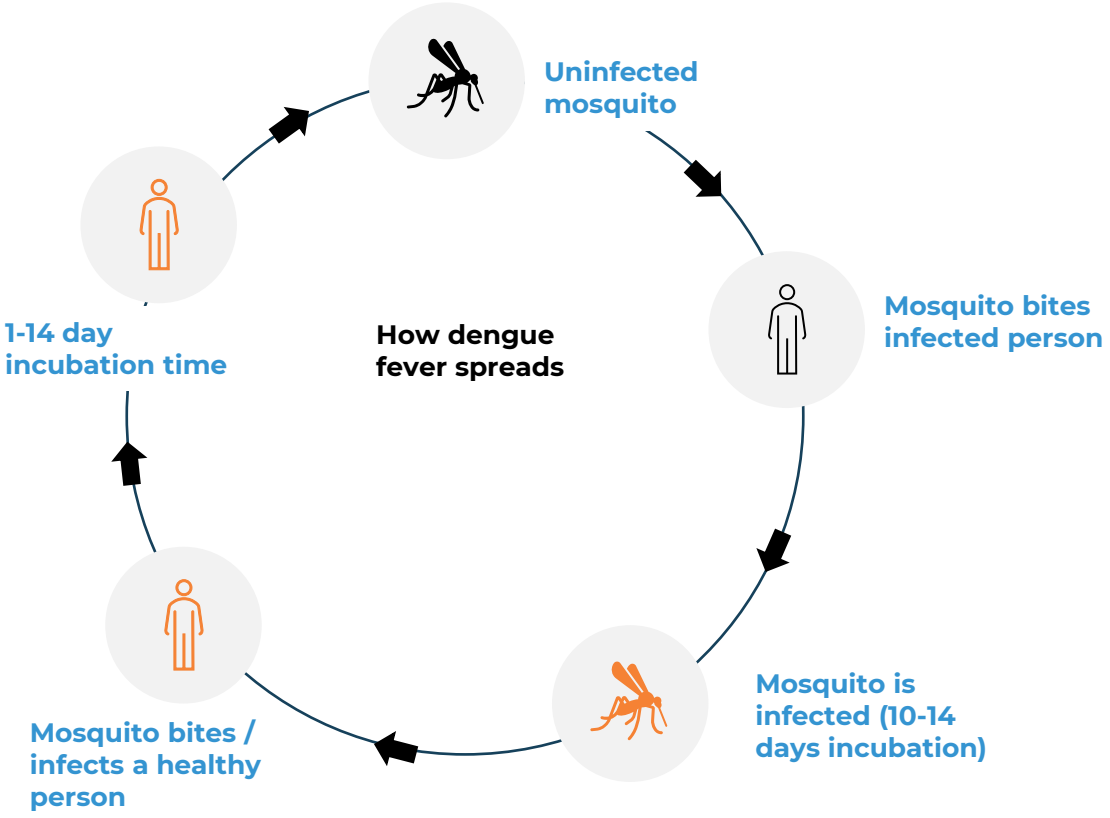
# DENGUE IN 2050 – A GLOBAL DISEASE

**Prediction based on projections of future temperatures, rainfall, and mosquito populations**




*NASA Earth Observatory map by Lauren Dauphin based on data from Janey Messina, University of Oxford - https://earthobservatory.nasa.gov/features/disease-vector*

# INFECTION AND SPREAD




## Why the surge in dengue infections?

**Warmer temperatures**

- Accelerate development
- Increase activity of female mosquitoes
- Reduce incubation time for mosquito to become infectious
- Allow mosquitoes to survive longer through winter

**High humidity**

- Improves mosquitoes' chance of survival

**Extreme weather**

- Disrupts water / sanitation
- Increased flooding can enhance breeding

“About half of the world's population is now at risk of dengue with an estimated 100–400 million infections occurring each year”

*World Health Organisation, 30 May 2024*

# About ISLA-101

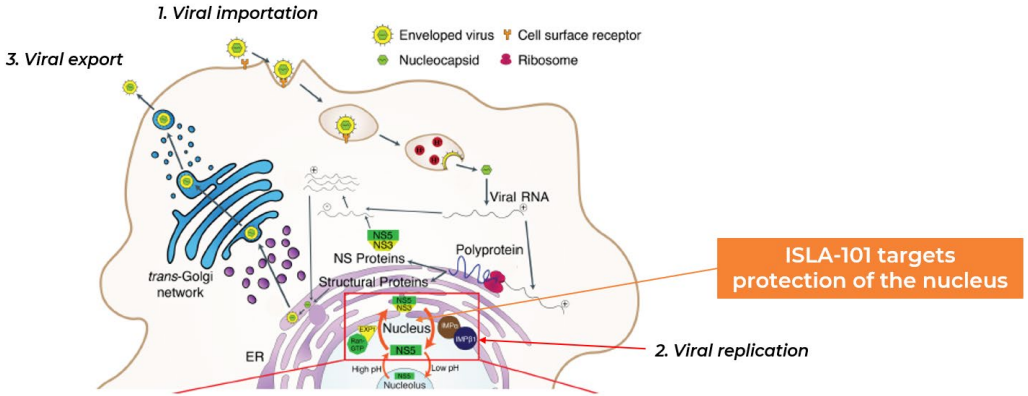
# ISLA-101 BROAD ACTIVITY EVIDENT

## Demonstrated activity against flaviviruses (a subgroup of arboviruses) in multiple models of infection


- In *in-vitro* models ISLA-101 has demonstrated broad anti-viral activity
- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated potent anti dengue-1 activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown to prevent death in 70% of subjects
- Increasing concentrations of ISLA-101 prevent death induced by an otherwise lethal dengue fever infection
- 45 HUMAN Clinical Studies of ISLA-101 completed in other indications
- *Island's own Single Ascending Dose study and further modelling reinforced safety / tolerability and identified Phase 2 dosing*

# ISLA-101 PREVENTS VIRAL REPLICATION

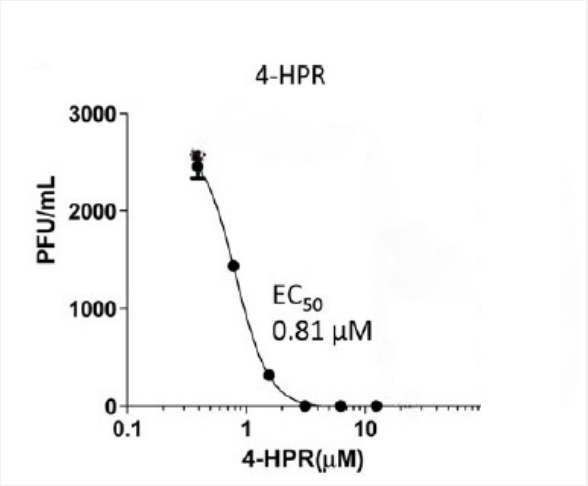
## Mechanism of action (how it works)




ISLA-101 inhibits propagation of flaviviruses

- To replicate, the virus needs to hijack the nucleus of the host cell
- Studies demonstrated ISLA-101 prevents this, therefore preventing virus replication
- Same mechanism of action for a therapeutic or prophylactic – either before or after exposure to the virus

## ISLA-101 reduces viral load[1]



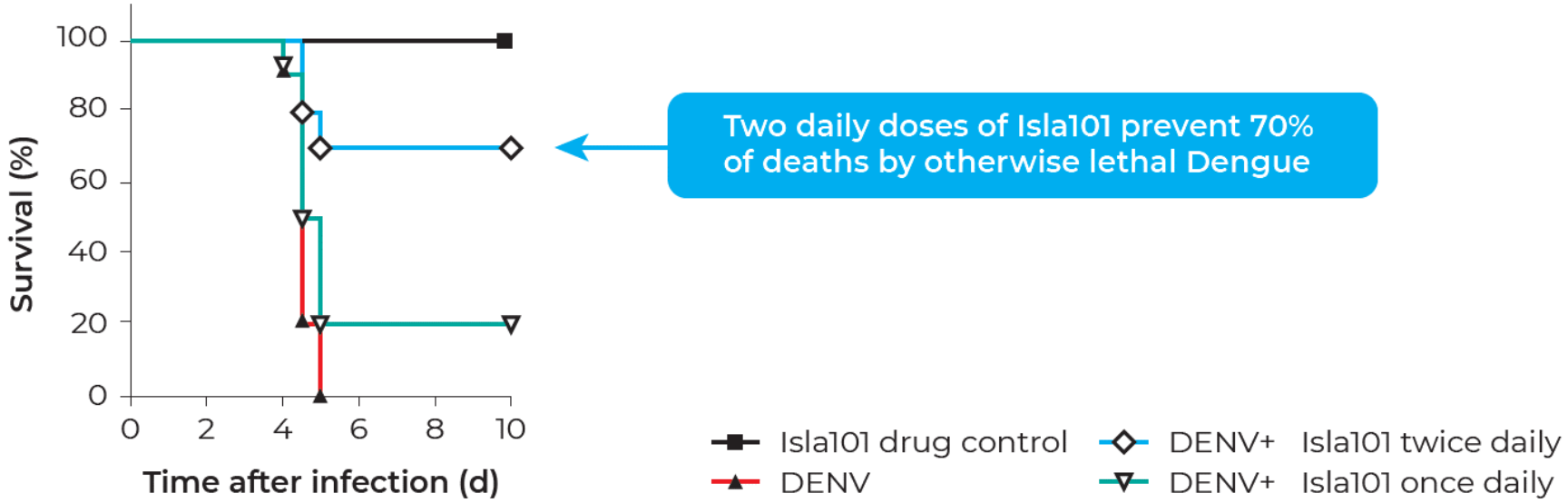

Above: dose response showing ISLA-101's ability to protect against dengue infection

- In freshly isolated human cells, ISLA-101 was shown to potently reduce viral infection with a sub micromolar $EC_{50}$
- Island's SAD study was designed to also investigate the ability to achieve appropriate blood concentrations in healthy human volunteers

*1. Fraser et al. J. Infect. Dis 2014*

# PREVENTS ANIMAL DEATHS FROM LETHAL DENGUE

ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.




Survival curve showing protection from lethal dengue change by Increasing dose of ISLA101 (mouse model).
*Fraser et al. J. Infect. Dis 2014*

# PHASE 2a/b DENGUE (PROTECT) TRIAL STUDY

**"PROTECT"** study- A Phase 2a/b, Randomized, Double blind, Placebo-controlled Dengue Challenge Study – a PROphylactic and TrEatment Challenge Trial

The study will be conducted at SUNY Upstate Medical University Syracuse, New York.

**Phase 2a/b trial protocol: 2 cohorts**

1. Prophylactic Cohort- 2A: 4 subjects randomized 3:1
2. Therapeutic Cohort: 2B: 10 subjects randomized 8:2

## Primary endpoint

- Assess the effect of ISLA 101 on clinical signs and symptoms after challenge with DENV-1-LVHC

## Secondary endpoints

- Characterize the clinical, immunologic and virologic responses following ISLA 101 after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

US$624k Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY to directly support PROTECT study.

# WHY A CHALLENGE STUDY?

*"When there are no available animal models of a disease, researchers take a weakened form of the virus and create a mild, safe form of the disease in a healthy person. The idea is that in a safe, well-controlled environment using a small number of people, we can get information that normally would involve going into the field and exposing a lot more people.*

*It is good timing for Island to test their product ISLA-101, now that it has successfully passed the Phase 1 safety study. The Phase 2 trial then can examine, in a small, very controlled and safe environment, if ISLA-101 has an impact on viral replication in humans, the symptoms, and the immune response."*

**Professor Stephen Thomas MD**
**Director, Update Global Health Institute**

# PHASE 2a/b CLINICAL TRIAL DESIGN

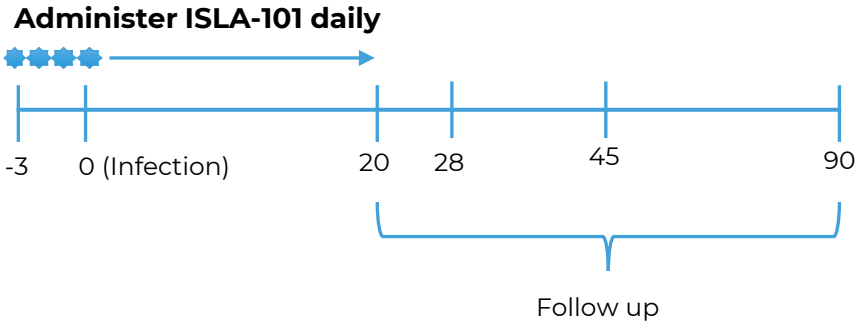
**Phase 2a/b trial protocol: 2 cohorts**

1. Prophylactic Cohort- 2a (left): 4 subjects randomized 3:1
2. Therapeutic Cohort: 2b (right): 10 subjects randomized 8:2

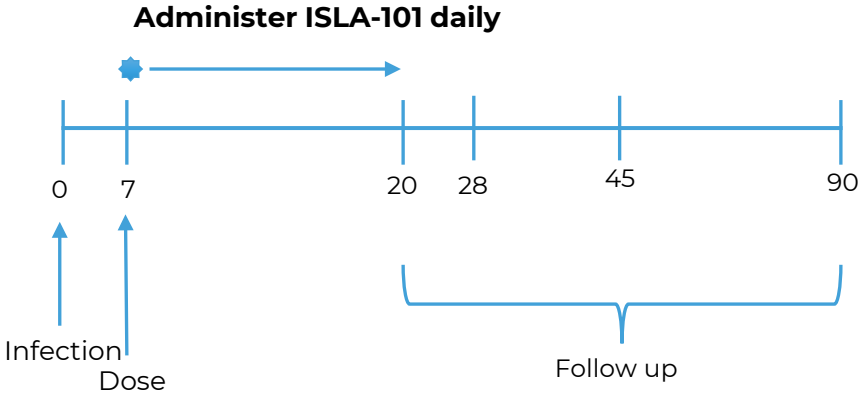
**Key near-term milestones:**

- Ethics approval received in August 2024, patient screening began in early September, with dosing expected to start imminently
- *Phase 2a read out expected by the end of 2024*
- *Phase 2b cohort dosing expected to commence in Jan 2025*

## Phase 2a: Prophylactic (preventative) cohort




## Phase 2b: Therapeutic (treatment) cohort

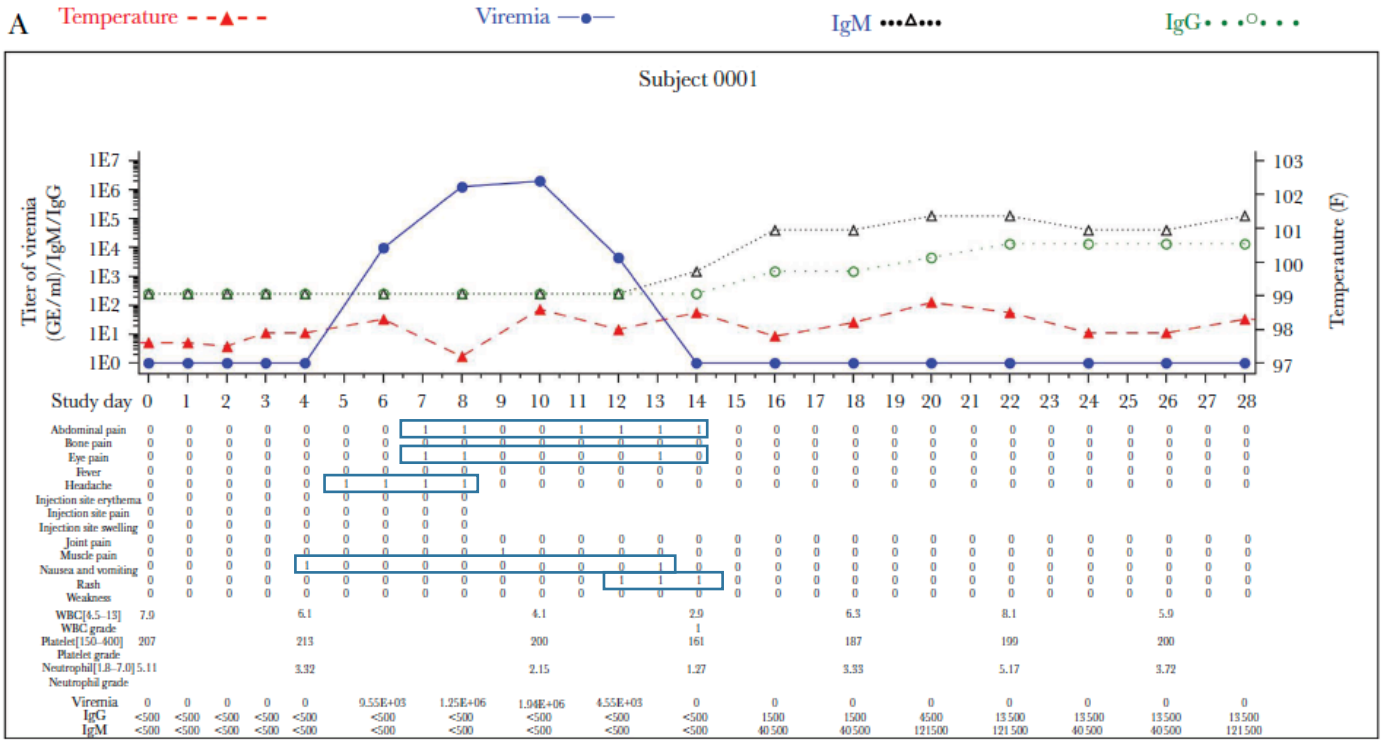


# PHASE 1 CONTROL DATA DEMONSTRATES BENEFIT OF CHALLENGE STUDY APPROACH

A Phase 1 challenge study conducted by Walter Reed and SUNY Upstate forms the basis of Island's PEACH study control data, and enabled unprecedented ability to monitor dengue symptoms, including:

- Abdominal pain
- Eye pain
- Fever
- Headache
- Nausea and vomiting
- Rash

Island will use the same attenuated virus and approach in its coming Phase 2 study.




Endy et al, J Inf Dis 2021

# STRATEGIC CHECKLIST

- Clinical history
- Small molecule
- Proven preclinical anti-viral activity
- Eligible for Priority Review Vouchers
- National and military preparedness need
- Probable/confirmed non-dilutive funding to support: military, civilian, NGO
- Fit for our management and advisory team: mid/late stage drug development, extensive medical countermeasures experience and roles


ISLAND
PHARMACEUTICALS
Antiviral therapeutics
PIPELINE BUILD, OPPORTUNITIES AND MILESTONES

# TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET

## GALIDESIVIR – Ebola, Marburg, Zika & and many other RNA viruses

- 12 month, **binding** Letter of Intent signed 11 September 2024
- Substantial Phase I human safety data
- Proven protective efficacy in a number of lethal animal models
- If proceed to full option agreement, would be seeking to confirm continued access to FDA's **Animal Rule**
- Extensive US government funding to date
- PRV eligible (multiple options)

# COMMERCIAL OPPORTUNITIES

## BOTH candidates have prophylactic and therapeutic potential

### Travellers

Malaria is also a mosquito borne disease and therefore a proxy for other tropical diseases. Market for anti-malarials is expected to reach US$1B[1] by 2026

### Military

Relationship with US Army in place (CRADA, ISLA101). Will continue discussions as programmes advance. Proven interest in both assets.

### National Outbreaks

Millions of patients in Latin America & Asia offer potential for sales in disease suppression and treatment during outbreaks of dengue, Zika. Increasing rapidly elsewhere.

### Government Stockpiles

Potential for countries to establish civilian and military drug stockpiles as happens with influenza.

### Priority Review Vouchers

Last ten PRVs sold for an average of US~$110M, with potential for ISLA-101 and galidesivir at the time of first FDA approval

1. *https://www.alliedmarketresearch.com/anti-malarial-drug-market*

# WELL-FUNDED FOR KEY INFLECTION POINTS

- Island has secured **A$3.5m in new funding** to support key inflection points in our clinical program and our pipeline build
- Two-tranche placement at 7 cents (A$0.07) a share. With one new option attached with every new share issued (with an exercise price of 7 cents (A$0.07), 50% expiring within 12 months of issue and 50% expiring 24 months of issue), subject to shareholder approval
- Supported by biotech investor, Dr Daniel Tillett and prominent Hong Kong-based fund manager, Angus Walker, together with Island co-founder and major investor, Dr Bill Garner; substantial shareholder Jason Carroll and recently appointed Non-Executive Director, Chris Ntoumenopolous
- Island in very strong position to complete the current Phase 2a/b study, with funding also to support the due diligence campaign for the Galidesivir antiviral therapeutic program and provide the acquisition funding if required

*"I have been invested in Island for many years and have been watching the company closely over that time. Island's impressive clinical progress with ISLA-101, along with the recent pipeline expansion into new antivirals, has created a compelling investment opportunity. The ability to leverage historical clinical data to advance overlooked antivirals in areas of great unmet need, combined with the potential value of acquiring two priority review vouchers upon approval, is highly attractive."*

***Dr Daniel Tillett***

# CORPORATE SNAPSHOT

## Key data

| | |
|---|---|
| Share price (AUD[1]) | $0.135 |
| Market cap[1] | $16.35m |
| Shares on issue[1] | 154,111,068 |
| Listed Options[2] | 32,384,597 |
| Cash at 30 June 2024[3] | $1.7m |
| Placement announced 3 October 2024 | $3.5m |
| DoD grant funding to directly support the Phase 2a/b PROTECT clinical study | USD $625k |

Substantial holders to be updated in coming weeks, following Placement settlement and substantial notice lodgement

## Recent ILA trading history


## Board of Directors

| |
|---|
| Dr Paul MacLeman, Executive Chairman |
| Dr David Foster, CEO and Managing Director |
| Mr Albert Hansen, Non-Executive Director |
| Dr Anna Lavelle, Non-Executive Director |
| Mr Chris Ntoumenopoulos , Non-Executive Director |

1.As at 4 October 2024 plus proposed issuance announced on 3 October 2024 | 2. ILAO Option terms: Exercise price of $0.06 expire 14 March 2025. | 3. As at 30 June 2024 – does not take into consideration cash burn since June 2024 or cash received from Placement and options exercised | 4. Shares held per 2024FY Annual Report, does not include participation in Placement announced 3 October 2024 | | 5. Does not include participation in Placement announced 3 October 2024 | Share price data sourced from asx.com.au

# KEY MILESTONES**

## H1 FY 2024 (Jul – Dec 2023)

- Key US and Australian patents granted for ISLA-101
- Obtain HREC (i.e. IRB) approval
- Screen, enrol and dose volunteers in Single Ascending Dose study
- Successful progression through Single Ascending Dose study cohorts

## H2 FY 2024 (Jan – Jun 2024)

- Dose final Single Ascending Dose study subject
- Single Ascending Dose study read out
- FDA interaction on Phase 2a/b study protocol
- Pipeline expansion efforts
- Complete in silico modelling of multiple dosing regimen

## H1 FY 2025 (Jul – Dec 2024)

- Obtain ethics approval for Phase 2 trial
- Screening subjects in Phase 2a/b trial
- **Subjects dosed in Phase 2a trial arm**
- **Secures $3.5M in funding to support key inflection points**
- Data readout from Phase 2a study
- **Ongoing DD on Galidesivir program**
- **Ongoing discussions with potential partners**

## H2 FY 2025 (Jan – Jun 2025)

- Subjects dosed in Phase 2b trial arm
- Data readout from Phase 2b study
- End of Phase 2a/b meeting anticipated with FDA
- Plans announced for next steps in clinical programs
- Ongoing discussions with potential partners

** Dates are indicative only, based on best estimates at the time of writing; subject to change.

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# SCIENTIFIC ADVISORY BOARD

## Dr Leigh Farrell

Leigh has over 30 years' experience in the biotechnology and pharmaceutical industry and is Head of Health Security Systems Australia, a Division of DMTC Ltd, is a non-executive director of Pro Medicus Ltd, Ena Respiratory Pty Ltd and Axelia Oncology ty Ltd, and is a member of the Walter and Eliza Hall Institute of Medical Research Board Commercialisation Committee and a member of the Independent Advisory Council of Medicines Australia.

Leigh's past appointments include: Senior Vice President, Commercial at Certara USA, Inc where he was responsible for Asia Pacific Commercial and global government engagement for the preparedness, planning and response to major health emergencies; Chairman & COO of d3 Medicine, LLC; Vice President of Business Development at Biota Pharmaceuticals Ltd, Research Manager Johnson & Johnson Research and CEO of Gene Shears Pty Ltd. Leigh holds a PhD in Biochemistry from Monash University.

## Prof Stephen Thomas MD

US WRAIR – SUNY Upstate
Professor Stephen Thomas, MD has an international leadership role as Lead Principal Investigator for Pfizer/BioNTech global Phase III COVID-19 vaccine trial now being deployed globally.

Prof. Thomas is a world-renowned virologist and vaccinologist and has authored numerous papers and articles on dengue fever, Zika and many other infectious diseases.

Chief, Division Of Infectious Diseases, New York Upstate Medical University; Professor of Medicine, Professor of Microbiology & Immunology, and Infectious Diseases physician-scientist from the State University of New York (SUNY), Upstate Medical University; Chief, Division of Infectious Diseases and Director, Institute for Global Health and Translational Science (IGHTS.)

He had twenty years in the U.S. Army Medical Corps serving at the Walter Reed Army Institute of Research (WRAIR.)

## Dr Amy Patick

BMS – Mayo Clinic
Amy Patick is a scientific consultant with deep expertise in antiviral drug discovery, development and viral resistance with broad know how in emerging virus epidemics and translational medicine.

Previously, Dr. Patick has served as Vice President, Research at Adamas Pharmaceuticals, Vice President, Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, Inc. and Research Scientist at Bristol-Myers Squibb Company. Dr. Patick has also served as President for the International Society of Antiviral Research.

Dr. Patick was a postdoctoral fellow in immunology at the Mayo Clinic/Foundation in Rochester, MN and received her PhD in Medical Microbiology from the University of Wisconsin, Madison.