

12 November 2024

ASX Announcement

Island investor roadshow presentation

MELBOURNE Australia, 12 November 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to share a copy of the presentation being delivered to investors during an Australian roadshow from this week.

During the roadshow, CEO & Managing Director, Dr David Foster will provide an update on the progress of the Phase 2a/b PROTECT clinical trial of Island's lead candidate, ISLA-101 in dengue fever. He will also discuss the binding term sheet in place for second potential asset, Galidesivir and the near-term milestones for both programs.

Group meeting opportunities will be available via:

- The investor information session, being held in Melbourne CBD this coming Friday, 15 November, 2024 from 10:15am AEDT.

(See ASX announcement dated 7 November 2024 for more details or email pip.thorne@irdepartment.com.au to register.)

- Island's Annual General meeting, being held in Sydney next Tuesday, 19 November, 2024 from 9:00am AEDT.

(See the Notice of Meeting lodged with ASX on 18 October 2024 for more information.)

Investors interested in setting up a 1:1 meeting with Island during the roadshow are invited to contact Jane Lowe via jane.lowe@irdepartment.com.au.

To subscribe to Island's monthly newsletter, *IslandWatch*, and other forms of email communications, please visit [this page](#) of our website.

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:

Jane Lowe
IR Department
Mobile: +61 411 117 774
jane.lowe@irdepartment.com.au

About Island Pharmaceuticals

Island (ASX: ILA) is a drug repurposing company, focused on areas of unmet need for antiviral therapeutics to address infectious diseases. Our lead asset is ISLA-101, a drug with a well-established safety profile, being repurposed for the prevention and treatment of dengue2 fever and other mosquito (or vector) borne diseases.

If ISLA-101 achieves FDA approval, and certain other criteria are met, Island may be eligible to obtain a "Priority Review Voucher" at the time of FDA approval. This means that as well as getting approval to manufacture and sell ISLA-101, the Priority Review Voucher (PRV) could permit Island to expedite the FDA approval process for a new drug or sell the PRV in a secondary market.

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 for more on Island.



ISLAND

PHARMACEUTICALS

Antiviral therapeutics

COMBATting URGENT VIRAL DISEASE THREATS

DR DAVID FOSTER, MANAGING DIRECTOR

November 2024

(ASX: ILA)

DISCLAIMER



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Financial data All dollar values are in Australian dollars (\$) or A\$) unless otherwise stated. Any financial data in this presentation is unaudited. **Past performance** The operating and historical financial information given in this presentation is given for illustrative purposes only and should not be relied upon as (and is not) an indication of the Company's views on its future performance or condition. Actual results could differ materially from those referred to in this presentation. You should note that past performance of the Group is not and cannot be relied upon as an indicator of (and provides no guidance as to) future Group performance.

Future performance

This presentation contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "propose", "goals", "targets", "aims", "outlook", "forecasts", "should", "could", "would", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Any indications of, and guidance on, future operating performance, earnings and financial position and performance are also forward-looking statements. Forward-looking statements in this presentation include statements regarding the Company's future growth options, strategies and new products. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions.

Forward-looking statements, including projections, guidance on future operations, earnings and estimates (if any), are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. No representation is given that the assumptions upon which forward looking statements may be based are reasonable. This presentation contains statements that are subject to risk factors associated with the Group's industry. These forward-looking statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to earnings, capital expenditure, cash flow and capital structure risks and general business risks.

No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company). In particular, but without limitation, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward looking statements in this presentation will actually occur. Actual operations, results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Any forward looking statements in this presentation speak only as of the date of this presentation.

Subject to any continuing obligations under applicable law, the Company disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this presentation to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based.

Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.

An aerial photograph of a tropical beach. The left side shows a sandy beach with several palm trees and some lounge chairs. The right side shows the turquoise ocean with white waves crashing onto the shore. The entire image is framed within a circular shape that is semi-transparent, allowing the text to be overlaid.

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 (ASX: ILA) AT A GLANCE



Dengue infects up to 400m per year*



Major market potential



Positive results in aggressive models



Phase 2a/b PROTECT clinical trial in dengue underway



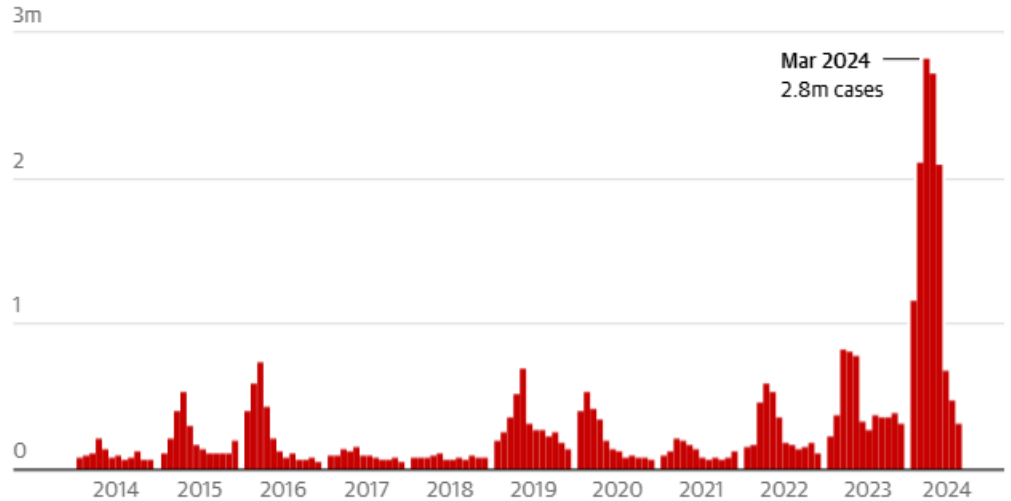
Priority Review Voucher potential



Pipeline expansion in progress

Global cases of dengue fever rose steeply in 2024

Monthly global cases, millions



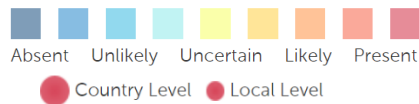
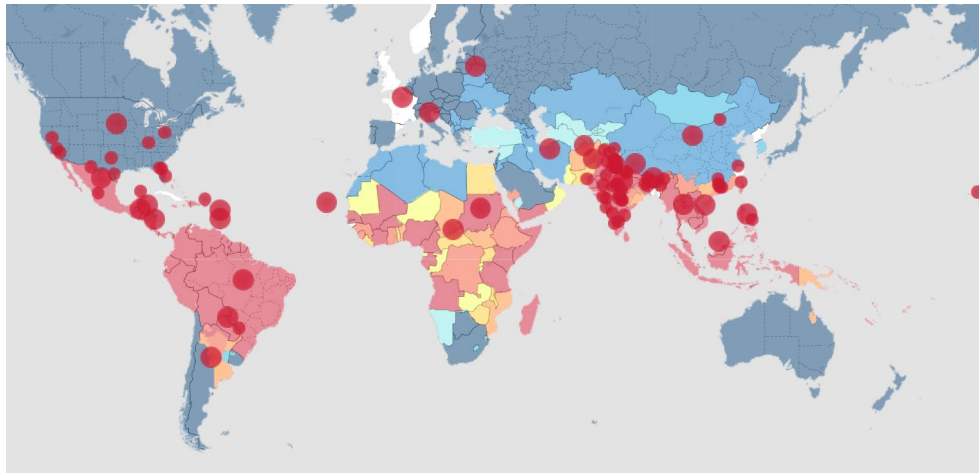
Guardian graphic. Source: WHO. Note: case reporting requirements vary by country

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 November 8, 2024

WORLD ECONOMIC FORUM [Join us](#)

CLIMATE ACTION

The world is in the grip of a record dengue fever outbreak. What's causing it and how can it be stopped?

Nov 5, 2024

Aus -

Sport Culture Lifestyle

Australia Middle East Africa Inequality Global development

Dengue fever: with a record 12.4m cases in 2024 so far, what is driving the world's largest outbreak?

Cases of 'bonebreak fever' are on the rise, mostly in Latin America, Africa and south-east Asia. But incidences in Europe and the US are also being recorded - with an estimated 4 billion people at risk worldwide

Advertisement

"A GRIPPING EXPERIMENT"

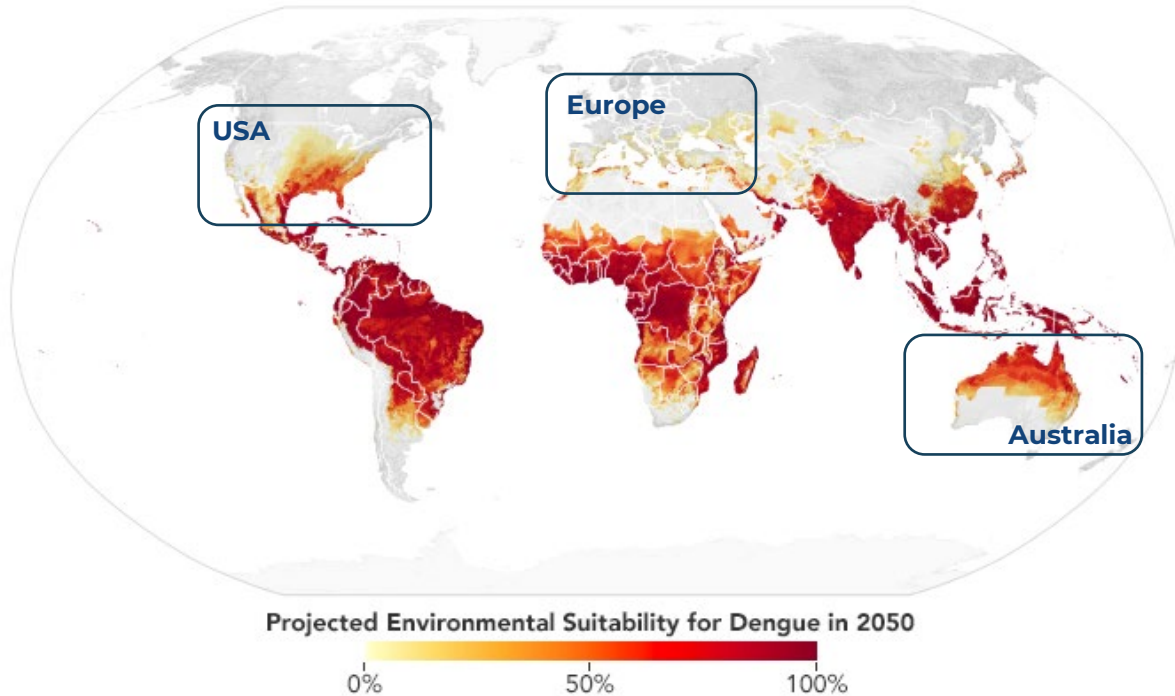
NEWS.COM.AU

THE JUR

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>

ENTER, THE TIGER MOSQUITO (*Aedes Albopictus*)



- A new mosquito, *Aedes Albopictus* is on the scene
- According to ECDC, the mosquito has been recorded as newly established in regions in France and Germany, and newly introduced into regions in Spain, the Netherlands, Portugal, and Slovenia.
- *The speed at which Aedes Albopictus* has contributed to the dengue problem was completely unexpected
- It is a warning for anyone NOT living in tropical areas that the dengue train is coming down the tracks

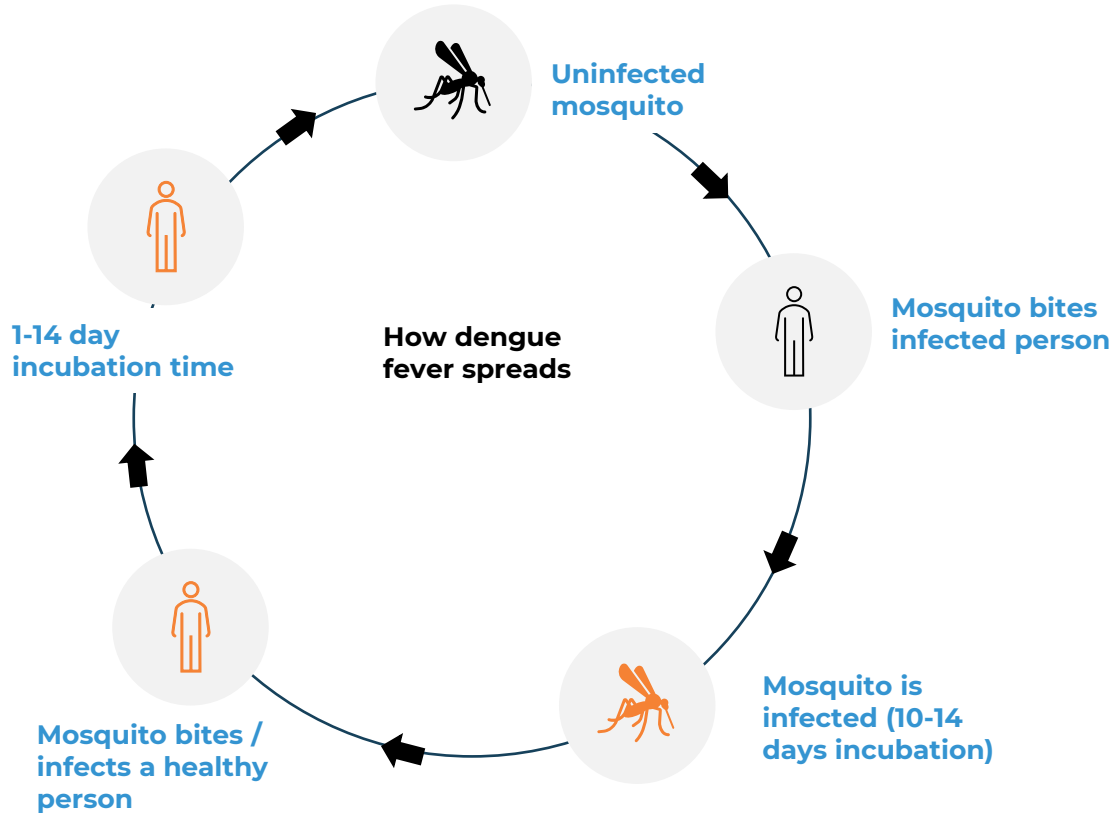
Additional analysis



*Figure 74: Percentage change in yearly average dengue estimated R_0 for *Aedes Albopictus* and *Aedes Aegypti* globally in the period 1950–2023.*

<https://www.ecdc.europa.eu/en/publications-data/aedes-albopictus-current-known-distribution-may-2024> | Figure 74 source: Supplement to: Romanello M, Walawender M, Hsu S-C, et al. The 2024 report of the Lancet Countdown on health and climate change: facing record-breaking threats from delayed action. *Lancet* 2024; published online Oct 30. [https://doi.org/10.1016/S0140-6736\(24\)01822-1](https://doi.org/10.1016/S0140-6736(24)01822-1).

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

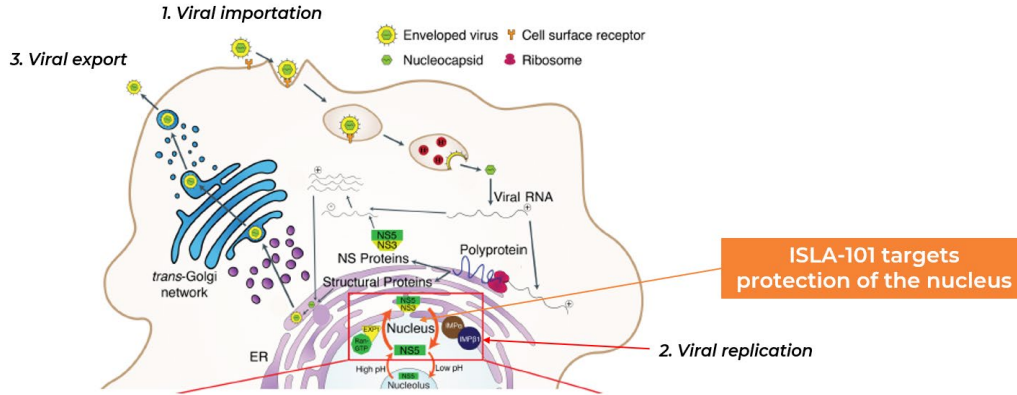


- In *in-vitro* models ISLA-101 has demonstrated broad anti-viral activity
- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated potent anti dengue-1 activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown 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)

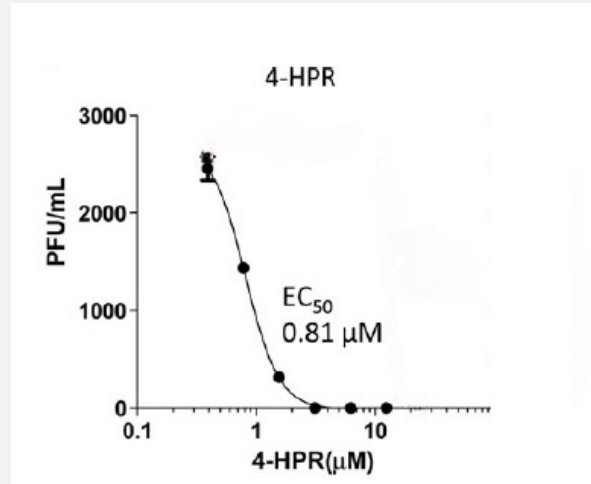


ISLA-101 inhibits propagation of flaviviruses

- 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

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

ISLA-101 reduces viral load¹



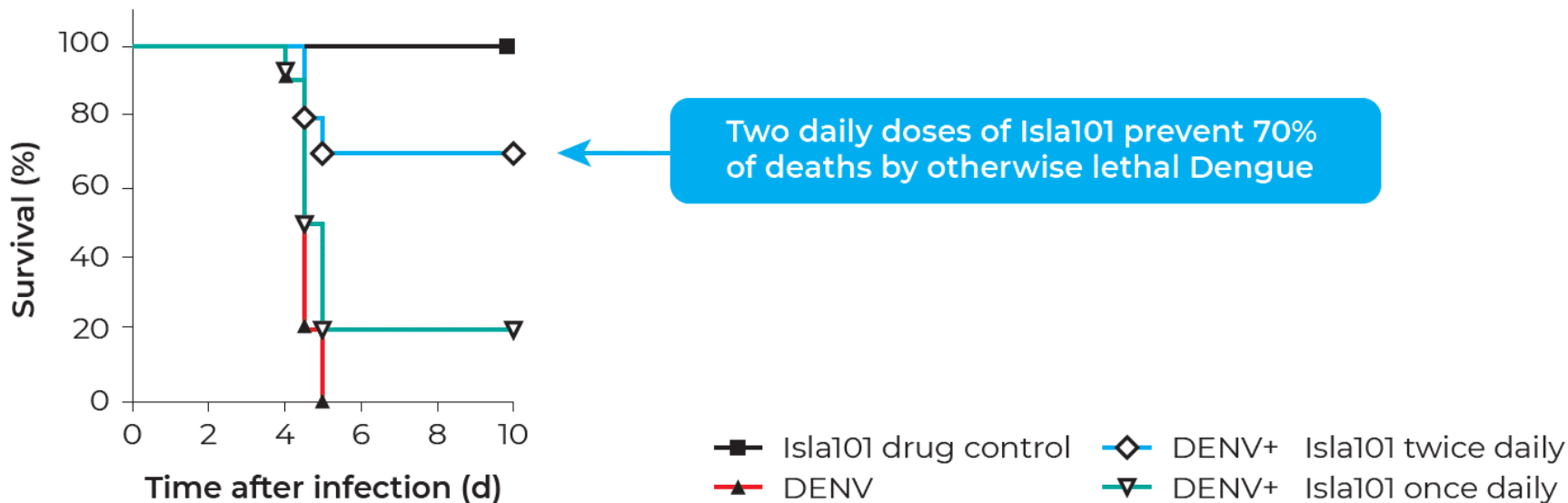
Above: dose response showing ISLA-101's ability to protect against dengue infection

- 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

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

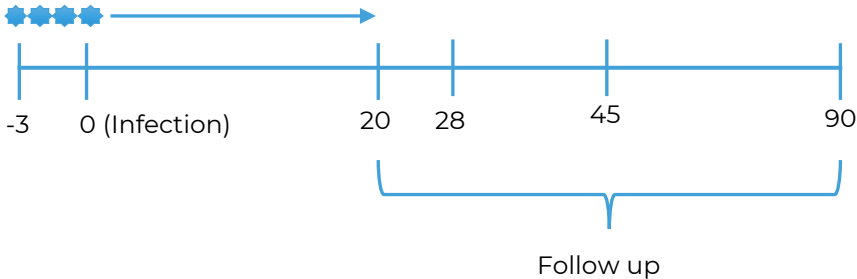
1. Prophylactic Cohort- 2a (left): 4 subjects randomized 3:1
2. Therapeutic Cohort: 2b (right): 10 subjects randomized 8:2

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*

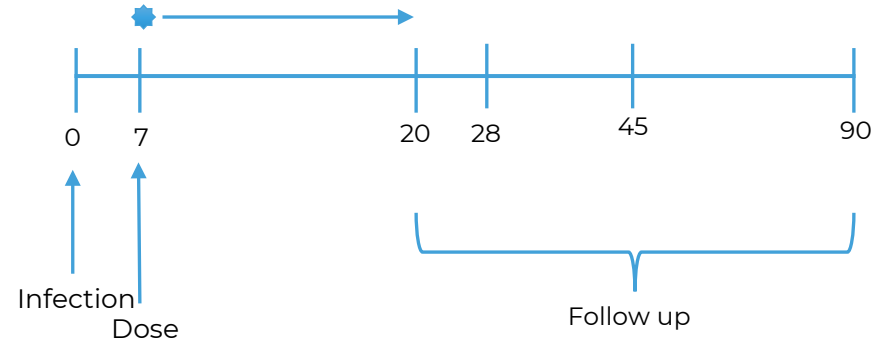
Phase 2a: Prophylactic (preventative) cohort

Administer ISLA-101 daily



Phase 2b: Therapeutic (treatment) cohort

Administer ISLA-101 daily



PHASE 1 CONTROL DATA DEMONSTRATES BENEFIT OF CHALLENGE STUDY APPROACH

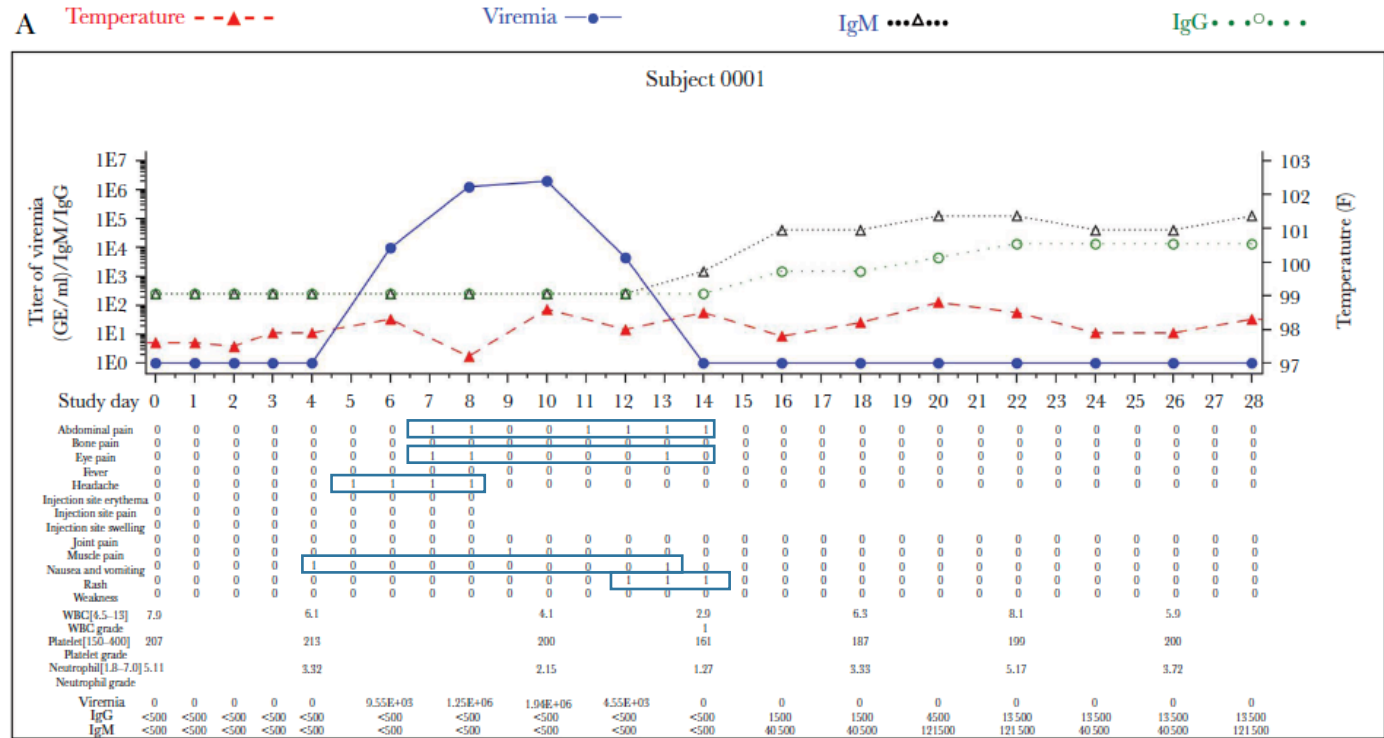


A Phase 1 challenge study conducted by Walter Reed and SUNY Upstate forms the basis of Island's PROTECT study control data, and enabled unprecedented ability to monitor dengue symptoms, including:

- 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\$1B¹ 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)	\$0.12
Market cap ¹	\$18.7m
Shares on issue ¹	155,900,709
Listed Options ²	30,594,956
Cash at 30 September 2024 ³	\$724k
Placement announced 3 October 2024	\$3.5m
DoD grant funding to directly support the Phase 2a/b PROTECT clinical study	USD \$625k
Substantial holders	
Dr William James Garner	18.24%
Jason Alan Carroll	16.24%
MWP Partners Limited	7.70%
Dr Daniel Tillett	5.26%

Recent ILA trading history



Board of Directors

Dr Paul MacLeman, Executive Chairman⁵

Dr David Foster, CEO and Managing Director

Mr Albert Hansen, Non-Executive Director

Dr Anna Lavelle, Non-Executive Director⁵

Mr Chris Ntoumenopoulos, Non-Executive Director

¹As at 8 November 2024 | ² [ILA Option terms](#): Exercise price of \$0.06 expire 14 March 2025. | ³ As at 30 September 2024 – does not take into consideration cash burn since 30 September 2024 or cash received from Placement and options exercised | ⁴ Shares held per Substantial interest notices lodged with ASX | | ⁵ As announced on 11 November 2024, Paul MacLeman and Anna Lavelle are resigning following the 2024 Annual General Meeting on 19 November 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.

Island Pharmaceuticals (ASX: ILA)



islandpharmaceuticals.com



[@IslandPharma](https://twitter.com/IslandPharma)



[Island Pharmaceuticals](https://www.linkedin.com/company/island-pharmaceuticals)



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.