



3 June 2024

ASX Announcement

Island presentation for Australian investor roadshow

MELBOURNE Australia, 3 June 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to release a copy of the presentation that will be delivered by Dr David Foster, CEO and Managing Director during investor meetings over the coming fortnight.

Highlights from the presentation include:

- Pharmacokinetic modeling updates, following the recent completion of Island's single ascending dose study
- Proposed updates to the approach for Island's Phase 2 clinical study for ISLA-101 in dengue fever

A copy of the presentation is appended to this announcement.

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:

Dr Paul MacLeman
Executive Chairman
Island Pharmaceuticals Ltd
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 WITH A KEY FOCUS ON DENGUE FEVER

JUNE 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.

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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 shore with several palm trees and thatched-roof huts. The right side shows the turquoise ocean with white waves crashing onto the shore. The entire image is framed within a large, semi-transparent circular overlay.

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



INVESTMENT HIGHLIGHTS



Addressing a high unmet need

Lead product ISLA-101 targeting dengue fever (lead indication) with further potential across a range of other mosquito-borne viruses: Zika, yellow fever and Chikungunya.

Significant market opportunity

Dengue fever infects up to 400m per year.* Endemic in >100 countries. Major market with no current pharmaceutical treatment. Potential preventative and therapeutic for travellers, military and governments.

Expanding clinical use cases

All endpoints achieved with recent Single Ascending Dose study. Data now being submitted to US FDA – Island is seeking to expand study to include both prophylactic and therapeutic arms (prev. focused on prophylactic alone.)

Eligible for high value PRV

Tropical diseases like dengue qualify under FDA's Priority Review Voucher scheme. Open to ISLA-101 at the time of FDA approval. Last ten PRVs sold for an average of US~\$110M – significant potential and relevance to Island.

Pipeline expansion underway

Targeting other viruses with significant unmet need and limited competition.

* WHO data – as at 30 May 2024: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

“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



DENGUE IS CLOSE TO HOME



10 ° 7' 24 "



news.com.au

Sign

National World Lifestyle Travel Entertainment Technology Finance Sport Shopping

Travel Updates > Travel Stories

Deadly viral infection doubles in popular tourists spots for Aussies

Known as the 'bone crushing fever', it made one Aussie model feel like she'd been "hit by a bus". Now, the virus is occurring in numbers never seen before.



Vanessa Brown

@vanessaibrown 4 min read May 26, 2024 - 8:02AM news.com.au

Source 1

yahoo!news

News Latest National World Environment

Bali tourists urged to follow simple measures after tropical disease cases 'double'

Not only is the virus causing people to fall extremely ill, in some instances, travel insurance costs can soar into the tens of thousands.



Brianne Tolj · Associate News Editor

Updated 21 May 2024 · 4-min read

Source 2

NBC NEWS

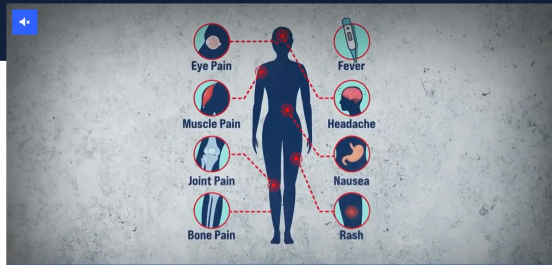
Dengue fever, once confined to the tropics, now threatens the U.S.

SHARE & SAVE - f X Email ...

HEALTH NEWS

Dengue fever, once confined to the tropics, now threatens the U.S.

Climate change is expanding the habitat of the mosquitoes that carry the disease, allowing them to spread further north.



Source 3

euronews.health

HEALTH HEALTHCARE NUTRITION WELLBEING SERIES

Home > Health > Health news

France warns of surge in imported dengue cases ahead of Olympics

Source 4

Article sources:

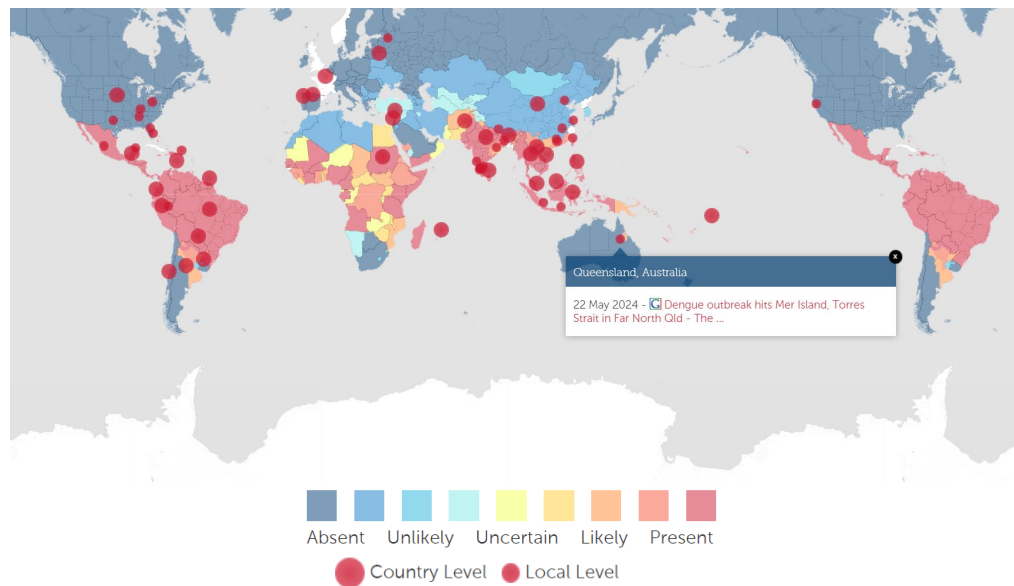
1. <https://www.news.com.au/travel/travel-updates/travel-stories/deadly-viral-infection-doubles-in-popular-tourists-spots-for-aussies/news-story/fc32fa4fc37eeled4ca48a4deb44f51c>
2. <https://shorturl.at/NsvwY>
3. <https://www.nbcnews.com/health/health-news/dengue-fever-climate-change-mosquitos-tropical-disease-rca149366>
4. <https://www.euronews.com/health/2024/04/24/france-warns-of-surge-in-imported-dengue-cases-ahead-of-olympics>

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 May 30, 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

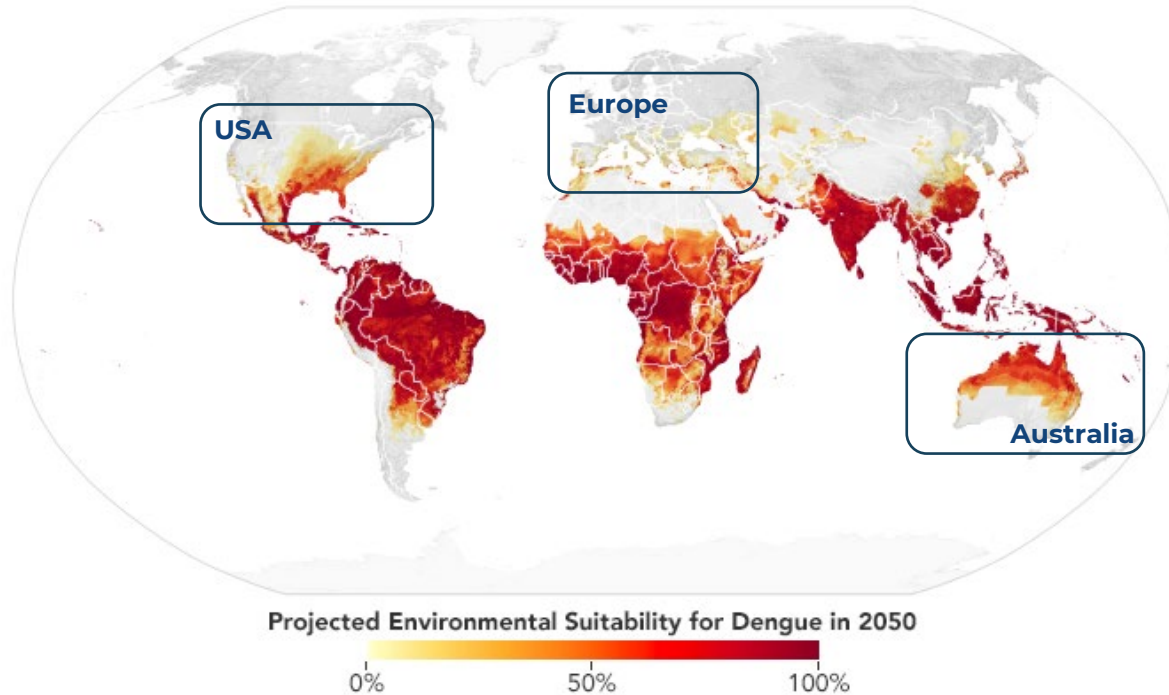
Dengue cases reach 647 in Barbados

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

DENGUE IN 2050 – A GLOBAL DISEASE

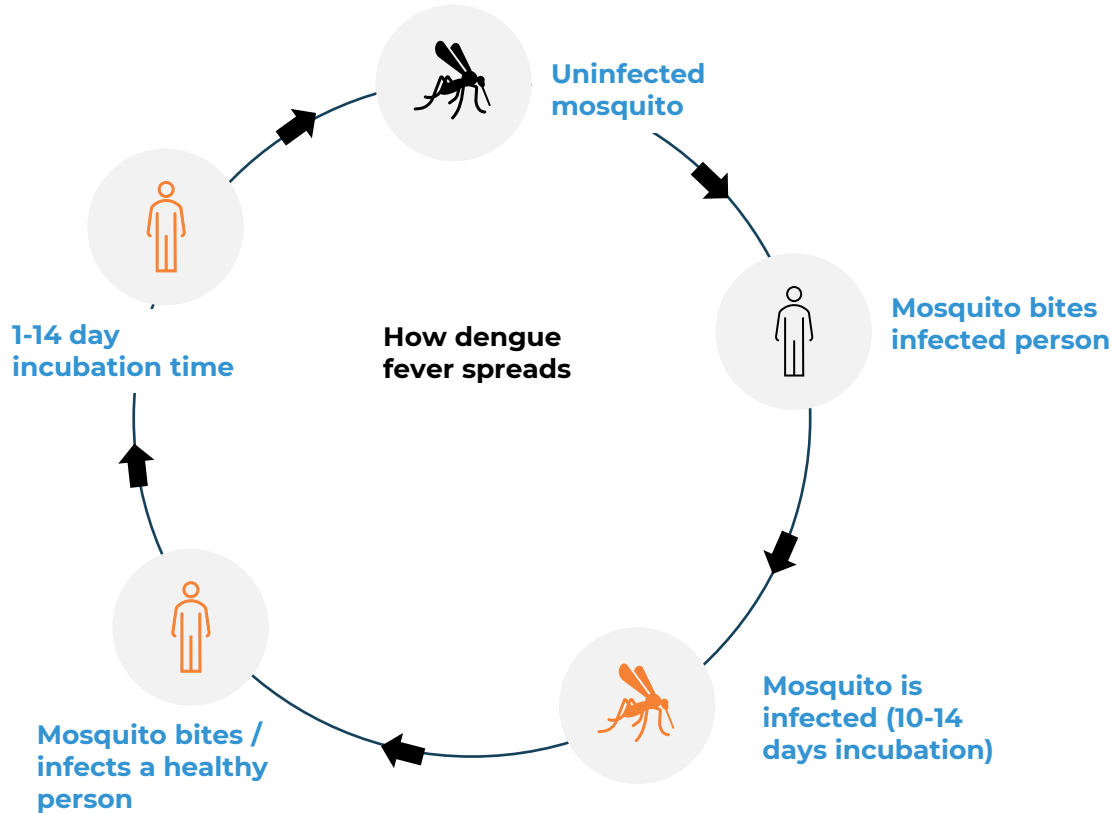


Prediction based on projections of future temperatures, rainfall, and mosquito populations



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

DENGUE CAN BE LETHAL IF NOT MANAGED ON TIME



It directly impacts both white blood cell count and platelets, which are vital for body protective mechanisms

Moderate symptoms:

- Headache
- Pain behind the eyes
- Nausea
- Vomiting
- Diarrhea
- High fever
- Rashes
- Muscle pain
- Flu-like symptoms
- Joint and muscle pain

Severe symptoms:

- Shock
- Severe pain in the stomach
- Blood pressure drops
- Severe bleeding
- Severe vomiting
- Difficulties affecting the heart, lungs or liver
- Bruising and pooling of blood under the skin
- Seizure

Diagnosis:

- Antibody detection
- Antigen detection
- RNA detection
- Viral isolation

Treatment:

- There is no specific treatment for dengue or dengue haemorrhagic fever
- Symptomatic relief (paracetamol etc) only.



US\$8.9B

Estimated impact to the economy from dengue fever

Prevention:

- Vaccines with limited availability
- Mosquito nets
- Insect sprays
- Wearing protective clothing (hard in hot climates)
- Fumigation
- Covering containers and showing vigilance around water

COMMERCIAL OPPORTUNITY



ISLA-101 has potential as both a prophylactic and therapeutic



Travelers

Malaria is also a mosquito borne disease and therefore a proxy for dengue. Market for anti-malarials is expected to reach US\$1B¹ by 2026



Military

Relationship with US Army in place for Phase 2 study (CRADA.) Will continue discussions as program advances



National Outbreaks

Millions of patients in Latin America offer potential for sales in disease suppression and treatment during outbreaks



Government Stockpiles

Potential for endemic countries to establish and maintain drug stockpiles as happens with influenza



Priority Review Voucher

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

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

About ISLA-101





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

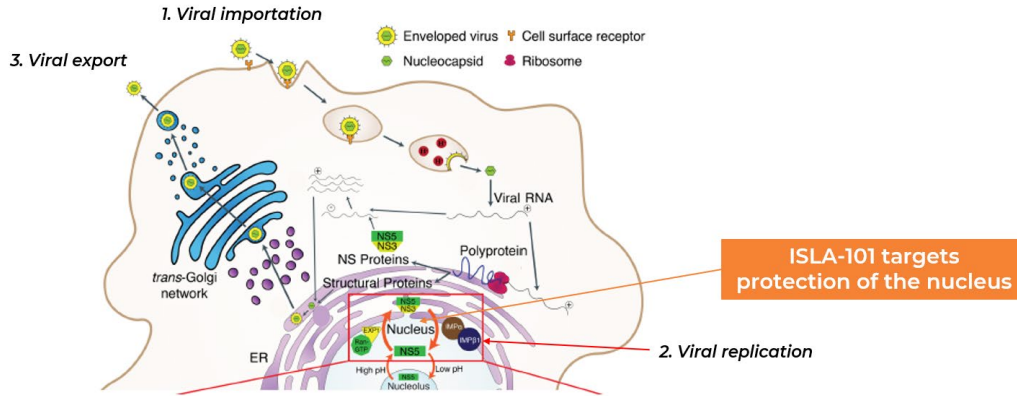


- In *in-vitro* models ISLA-101 has demonstrated broad anti-viral activity
- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated potent anti dengue-1 activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown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

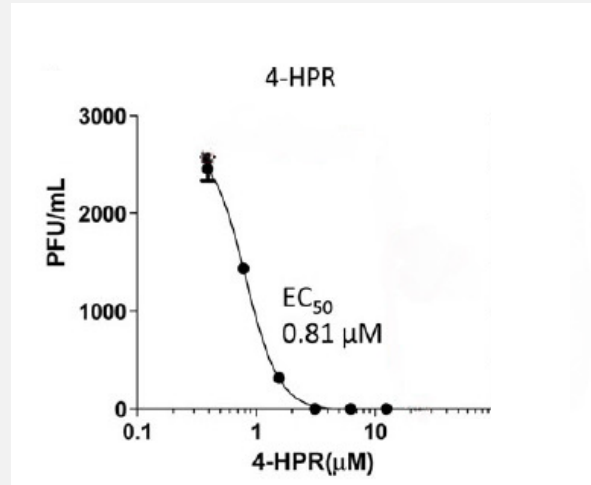


ISLA-101 inhibits propagation of flaviviruses

- 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



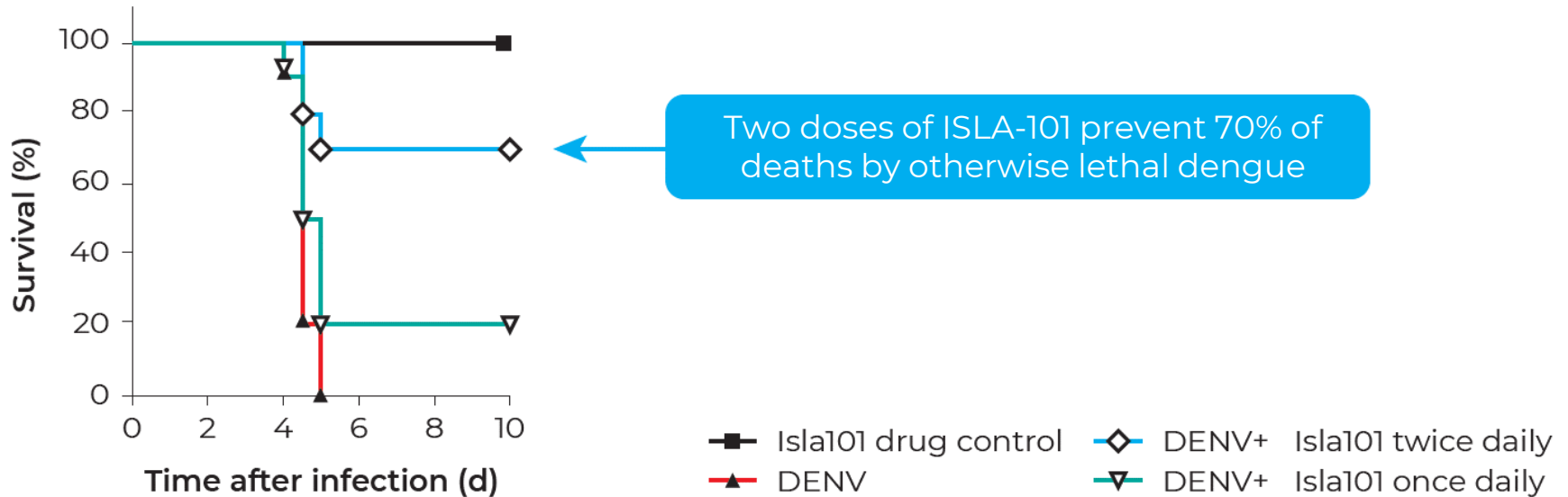
Above: dose response showing ISLA-101's ability to protect against dengue infection

- In freshly isolated human cells, ISLA-101 was shown to potently reduce viral infection with a sub micromolar EC₅₀
- Island's SAD study was designed to also investigate the ability to achieve appropriate blood concentrations in healthy human volunteers (slide 16)

ISLA-101 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 challenge by increasing dose of ISLA101 (mouse model).

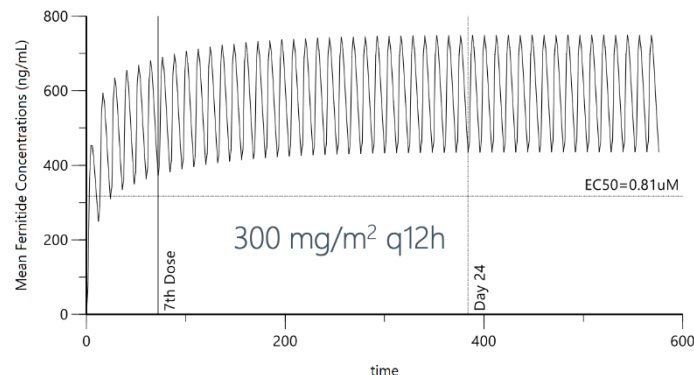
Fraser et al. *J. Infect. Dis* 2014

SINGLE ASCENDING DOSE STUDY DATA ACHIEVES ENDPOINTS, CONFIRMS PHASE 2 PLAN



- Island completed a 24-subject Single Ascending Dose study for ISLA-101 in early 2024, with highly positive outcomes:
 - ✓ ISLA-101 was safe and well tolerated
 - ✓ Data analysis showed required levels of ISLA-101 concentration in the blood were observed after only a single dose, achieving the study's purpose
 - ✓ Reinforcing the drug's safety and tolerability, in this study, Island dosed at levels equivalent to up to 10x the dose given in successful preclinical animal models (adjusted for differences in species)
 - ✓ Also helped to build our experience with the drug, manufactured at today's standards and in a modern clinical setting
- Post study in silico modelling confirmed the appropriate single, multi-day dose of 600 mg/m²/day (300 mg/m² twice daily) for the coming Phase 2 study, enabling Island to be more targeted with dosing, and in turn reducing timeline / cost structure
- Predicted blood concentration of ISLA-101 was 1.5 μM, well above calculated EC50 demonstrated to be effective in human cells (0.81 μM)

Data modelling predicts 300 mg/m² twice daily dose for Phase 2 study



ISLA-101 DEVELOPMENT MILESTONES



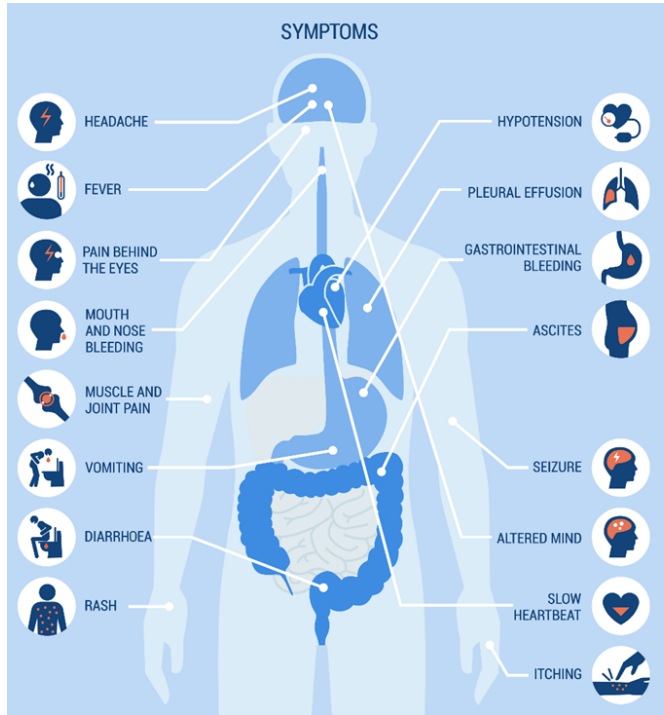
- With data from the Single Ascending Dose study in hand, Island now plans to interact with the US FDA regarding the study outcomes and strategies for how to maximise the data obtained from the Phase 2 study
- Plan is to incorporate a proposed therapeutic arm into the Phase 2 study, as well as the originally planned prophylactic arm
- Based on in silico modelling data, protocol expected to be single-level, multi-day dose (rather than multiple ascending dose per original plans)
- Plan is to incorporate a proposed therapeutic arm into the Phase 2 study, as well as a modified prophylactic arm
- Revised protocol being submitted to FDA
- Island has agreements and study partners in place for the study, so would expect it to commence quickly following submission of revised protocol
- Trial costs being finalised – further information to be released shortly



WHY TARGET DENGUE FIRST?



Significant unmet need for disease with increasing incidence



Significant unmet need (3.9 billion people at risk)

Increasing spread to US, EU and Australia

ISLA-101 has both therapeutic and prophylactic potential

Strong animal and human model results

First claim then spring board into other viral diseases

Priority Review Voucher eligibility

LIMITED SOLUTIONS



	Dengue fever	West Nile	Zika Virus	Yellow Fever	Japanese encephalitis	Comments
Worldwide prevalence	400 million	n/a	Up to 1.5 million	130,000	70,000	Viral diseases are a leading cause of hospitalization and death
Effective drug therapy available?	No	No	No	No	No	Other drugs have been explored in clinical trials but none approved. J&J is in Phase 2 with a dengue-specific anti-viral; Atea recently canceled their program following unsuccessful trials.
Vaccine available?	Limited	No	No	Limited	Limited	Vaccine development has been wrought by years of failures. Challenge is that the vaccine needs to protect against all 4 strains of dengue to an equivalent level. Sanofi has an approved vaccine that was approved following controversial clinical trials. It currently has a very limited label. Takeda is developing a vaccine that is being approved but does not equally protect against all 4 strains of dengue.



Deformities in babies from mothers with Zika

BUILDING OUR PIPELINE



- In addition to ISLA-101, Island is exploring the acquisition or in-licensing of new drug candidates
- Specific screening and scoring criteria being applied, based in part on the following criteria:
 - small molecule program
 - anti-viral
 - eligible for a Priority Review Voucher
 - national and military preparedness focus
 - possible non-dilutive funding to support clinical studies.



CORPORATE SNAPSHOT



Key data

Share price (AUD ¹)	\$0.075
Market cap ¹	\$8.59m
Shares on issue ¹	114,536,544
Options with piggy-back right ²	31,746,700
Cash ³	\$1.6m

Board of Directors

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

Recent ILA trading history



Substantial shareholders

Shareholder	Ownership ⁴
Dr William James Garner	22,056,105 (19.26%)
Mr Jason Alan Carroll	20,000,000 (17.46%)
Albert Hansen / Kesa Partners	11,104,034 (9.69%)

Ownership breakdown

- Top 20¹: 73.77%
- Board and management¹: 15.11%

1. As at 29 May 2024 | 2. [ILA Option terms](#): Exercise price \$0.06 expire 14 March 2025. [Piggy Back Right](#): If the Options are exercised on or before 14 June 2024, optionholders will be issued one Further Option (Piggy Back Option) for every Option exercised on the same terms | 3. As at 31 March 2024 – does not take into consideration cash burn since March or injections from option conversions | 4. Shares held per ASX lodged substantial holder notices | Share price data sourced from [asx.com.au](https://www.asx.com.au)

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 and a Bachelor of Science (Honours) from Monash University and is a Fellow of the Australian Institute of Company Directors.



Prof Stephen Thomas MD

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

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.

UPCOMING MILESTONES**



H1 FY 2024 (Jul – Dec 2023; Completed)

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

H2 FY 2024 (Jan – Jun 2024)

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

H1 FY 2025 (Jul – Dec 2024)

- Initiate Phase 2 trial
- First patient dosed in Phase 2 trial
- Advances through Phase 2 study cohorts
- Continue pipeline expansion efforts
- Ongoing discussions with potential partners

H2 FY 2025 (Jan – Jun 2025)

- Data readout from Phase 2 study
- End of Phase 2 meeting anticipated with FDA
- Plans announced for next steps in clinical program
- Ongoing discussions with potential partners

RECAP: FILLING A FAST-GROWING UNMET NEED



Addressing a high unmet need

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Island Pharmaceuticals (ASX: ILA)



islandpharmaceuticals.com



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