



**22 April 2024**

ASX Announcement

## **Island presentation for Asia BIO partnering conference and Hong Kong / Singapore roadshow**

MELBOURNE Australia, 22 April 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 to potential investors and partners in Hong Kong and Singapore this week.

Highlights from the presentation include:

- An overview of ISLA-101, Island's lead clinical stage asset for dengue fever
- An update on the significant problem presented by dengue fever both in South East Asia and globally
- Takeaways from the recently completed Single Ascending Dose study, where Island achieved all study outcomes relating to safety and dosing which enable the company to move forward with next steps regarding its Phase 2 study
- The next steps for the ISLA-101 clinical program and
- Other pipeline opportunities

Dr Foster will be presenting to the Asia Bio Partnering Forum in Singapore, where biotech and pharma leaders from around the world will gather to meet with biotech innovators. He will also be undertaking investor meetings in both Singapore and Hong Kong.

A copy of the presentation is appended to this announcement.

### **Approved for release to the ASX by:**

Dr Paul MacLeman  
Executive Chairman  
Island Pharmaceuticals Ltd  
[info@islandpharmaceuticals.com](mailto: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](mailto: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 dengue<sup>2</sup> 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, Automic 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.



**ISLAND**

PHARMACEUTICALS

Antiviral therapeutics

# COMBATTING URGENT VIRAL DISEASE THREATS WITH A KEY FOCUS ON DENGUE FEVER

APRIL 2024

(ASX: ILA)

# DISCLAIMER



This presentation has been prepared by Island Pharmaceuticals Limited (ABN 641 183 842) (**Company or Island Pharmaceuticals**).

## **Not an offer or financial product advice**

The Company is not licensed to provide financial product advice. This presentation is not and should not be considered, and does not contain or purport to contain, an offer or an invitation to sell, or a solicitation of an offer to buy, directly or indirectly any securities, to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful nor shall it (or any part of it), or the fact of its distribution, form the basis of, or be relied on in connection with or act as any inducement or recommendation to enter into, any contract whatsoever relating to any securities. This presentation is for information purposes only and is not a prospectus, product disclosure statement, pathfinder document for the purposes of section 734(9) of the Australian *Corporations Act 2001* (Cth) (**Corporations Act**) or other offer document under Australian law or the law of any other jurisdiction. This presentation does not constitute an invitation to apply for or purchase Securities and does not include any application form for Securities. This presentation does not constitute an advertisement for an offer or proposed offer of Securities. Neither this presentation nor anything contained in it shall form the basis of any contract or commitment and it is not intended to induce or solicit any person to engage in, or refrain from engaging in, any transaction. Nothing in this presentation constitutes legal, financial, tax or other advice. Recipients of the presentation should conduct their own investigation, evaluation and analysis of the business and other data and information set out in the presentation.

**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**

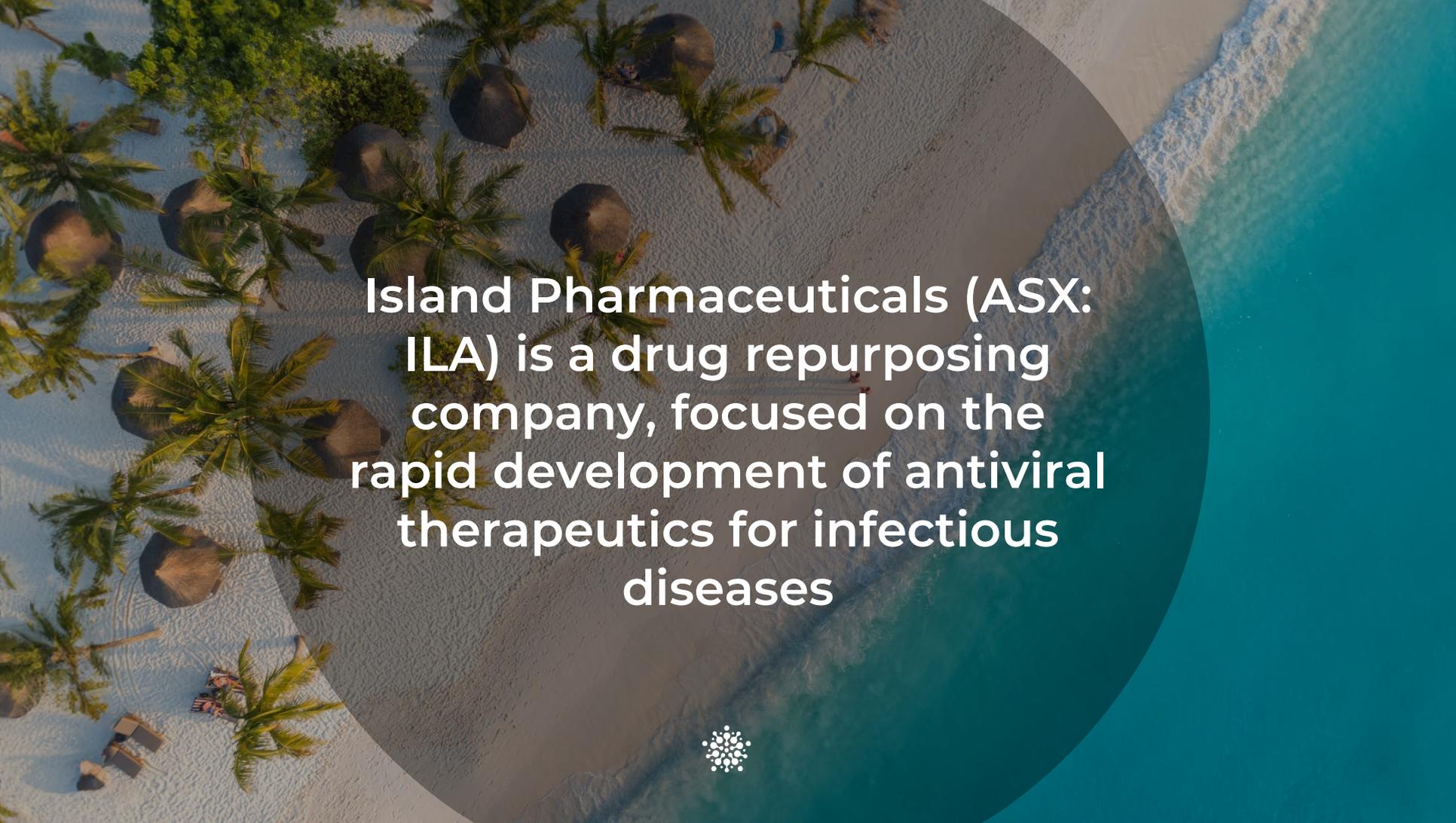
This presentation contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "propose", "goals", "targets", "aims", "outlook", "forecasts", "should", "could", "would", "may", "will", "predict", "plan" and other similar expressions are 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 with white sand, palm trees, and turquoise water. A large, semi-transparent circular graphic is overlaid on the right side of the image, containing white text. At the bottom center of the circle is a small white logo consisting of a cluster of dots.

**Island Pharmaceuticals (ASX:  
ILA) is a drug repurposing  
company, focused on the  
rapid development of antiviral  
therapeutics for infectious  
diseases**



# ISLAND AT A GLANCE



Dengue infects up to  
400m per year\*



Major market  
potential



Positive results in  
aggressive models

Now **endemic in more than 100 countries, as well as previously untouched countries** with no current pharmaceutical treatment.

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

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



Completed Single  
Ascending Dose study



Priority Review  
Voucher potential



Pipeline expansion  
underway

Achieving highly positive key study outcomes.

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

Targeting other viruses with **significant unmet need and limited competition**.

\*WHO, 17 March 2023.

**“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, 17 March 2023*



# DENGUE IN SINGAPORE

THE STRAITS TIMES

SINGAPORE

LOG IN SUBSCRIBE PDF

## Dengue cases on the up in Singapore; patients say the illness can be dreadful



More than 5,500 people here have contracted dengue in the first 14 weeks of 2024. ST PHOTO: KUA CHEE SIONG

Source 1

Article sources:

- <https://www.straitstimes.com/singapore/health/dengue-cases-on-the-up-in-singapore-patients-say-the-illness-can-be-dreadful#:~:text=Already%2C%20more%20than%205%2C500%20people,were%20six%20deaths%20that%20year>
- <https://www.precisionvaccinations.com/2024/04/01/singapores-dengue-outbreak-doubles-2023>
- <https://www.channelnewsasia.com/singapore/dengue-fever-cases-double-first-quarter-2024-mosquito-urgent-action-needed-4232836>

Home Dengue Flu Measles RSV STD Travel Vaccines

## Singapore's Dengue Outbreak Doubles 2023

April 1, 2024 • 2:43 pm CDT



START YOUR MOZZIE WIPEOUT

Singapore National Dengue Prevention Campaign 2024

(Precision Vaccinations News) – According to the World Health Organization, Dengue is endemic in over 100 countries in 2024, including the Republic of Singapore.

Source 2

Top Stories Latest News Discuss Singapore Asia Commentary Sustainability CNA Insider Lifestyle Watch Listen All Sections

## Dengue cases soar, doubling in first quarter of 2024; seven deaths reported

"Continued urgent action" is needed to prevent a surge in dengue cases this year, said NEA.



Adult dengue mosquitoes are pictured at a laboratory. (The photo: AFP/Lois Robbays)

Listen to this article

The audio is generated by an AI tool.

SINGAPORE: Singapore is experiencing a surge in dengue infections, with cases in the opening quarter of the year more than double that of the same period in 2023.

Over 5,000 dengue cases were reported, a spike from the 2,360 cases in the same quarter last year, according to the National Environment Agency (NEA) in a news release on Sunday (Mar 31).

31 Mar 2024 09:48 AM

Updated: 31 Mar 2024 04:48 PM

Share

Facebook Twitter LinkedIn Email Print

Related Topics

Dengue

National Environment Agency

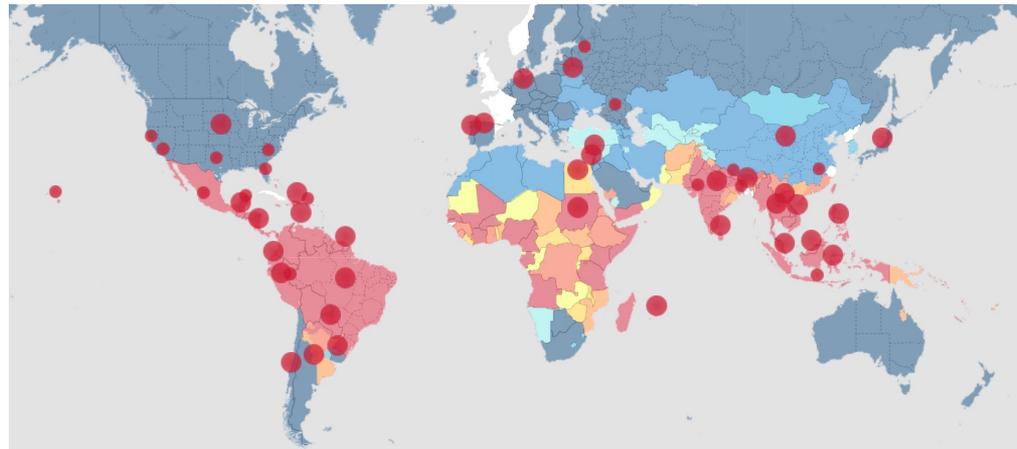
Source 3

# 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 April 17, 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**

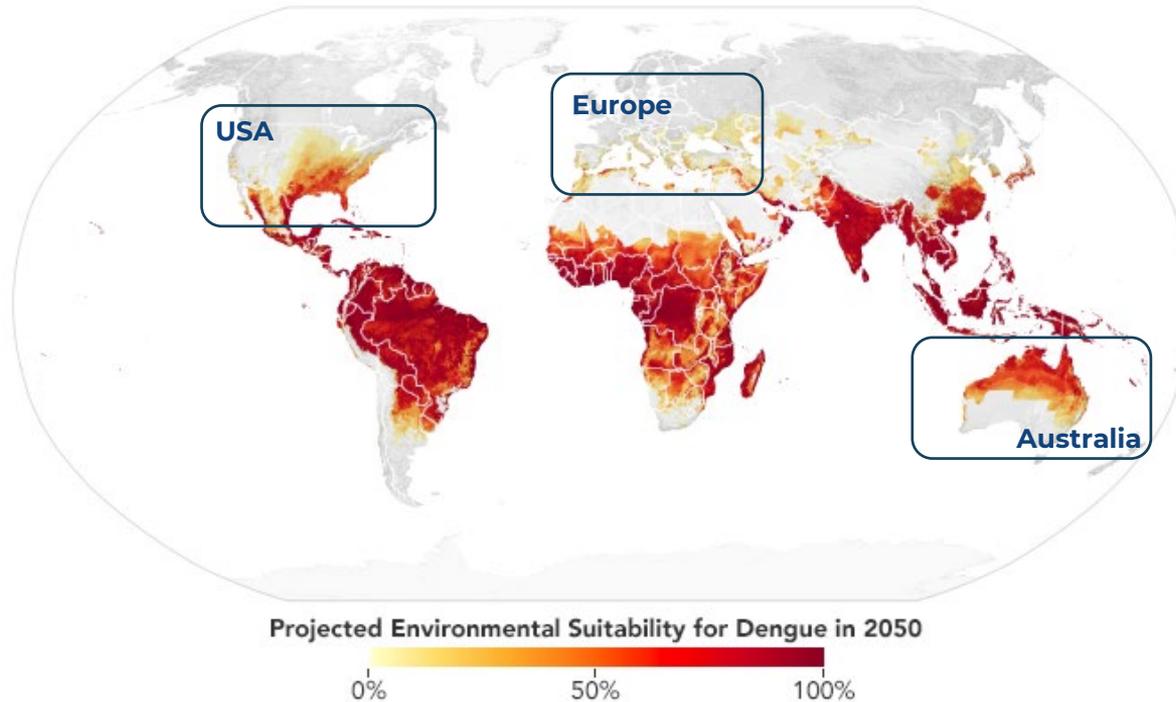
**Dengue cases reach 647 in Barbados**

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>

# COMMERCIAL OPPORTUNITY



ISLA-101 has potential as both a prophylactic and therapeutic



## Travelers

The malaria market, expected to reach US\$1B by 2026<sup>1</sup>, is expanding to an increasing number of countries



## Military

Partnering with army (CRADA in place) for Phase 2a clinical trial in Dengue Fever, to be pursued as Isla-101 is closer to approval



## 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>

# Introducing ISLA-101





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

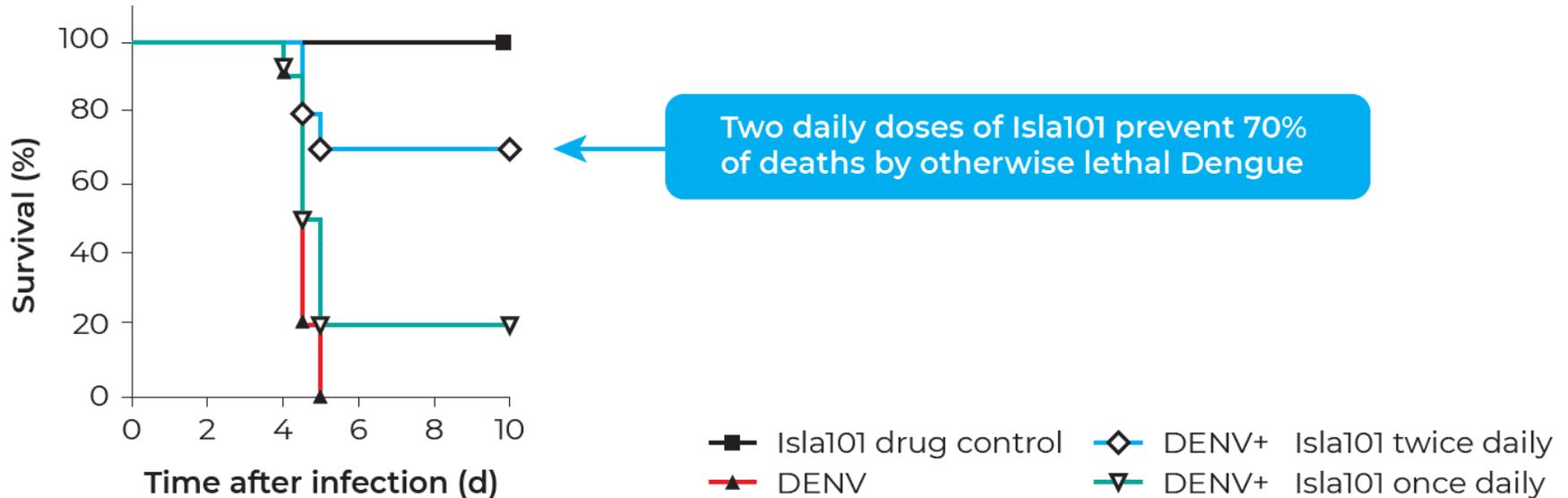


- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated broad anti-viral activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown to prevent death in 70% of subjects
- Increasing concentrations of ISLA-101 prevent death induced by an otherwise lethal dengue fever infection
- 45 HUMAN Clinical Studies of ISLA-101 completed in other indications

# 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 change by increasing dose of ISLA101 (mouse model).  
*Fraser et al. J. Infect. Dis 2014*

# SINGLE ASCENDING DOSE STUDY NOW COMPLETE



- Island completed a 24-subject Single Ascending Dose study for ISLA-101 in early 2024
- Study outcomes were highly positive:
  - ✓ ISLA-101 was shown to be 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

**Island (ASX:ILA)  
reports highly positive  
pharmacokinetic data  
from ISLA-101 Single  
Ascending Dose study**



**The study outcomes confirm  
that Island has an appropriate  
plan as we head toward the  
Phase 2 trial**

# ISLA-101 DEVELOPMENT MILESTONES



- With data from the Single Ascending Dose study in hand, Island now plans to interact with the US FDA to discuss the study outcomes and strategies for how to maximise the data obtained from the PEACH\* study
- The PEACH study protocol may then be amended based on FDA feedback
- Island has agreements and study partners in place for the PEACH study, so would expect to commence the study quickly once FDA feedback has been incorporated into the protocol

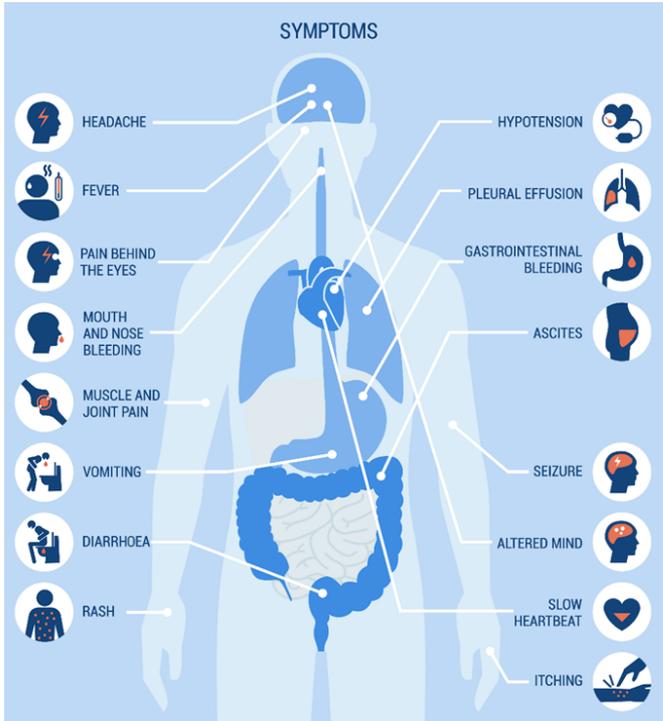


\* The “PEACH” study – a Phase 2a, Randomized, Double blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model, will be run at SUNY Upstate Medical University Syracuse, New York

# WHY DENGUE DISEASES?



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 AVAILABLE SOLUTIONS



**Worldwide prevalence**



**Effective drug therapy**



**Vaccine**

Dengue fever	West Nile	Zika Virus	Yellow fever	Japanese Encephalitis
--------------	-----------	------------	--------------	-----------------------

400 million	n/a	Up to 1.5 million	130,000	70,000
-------------	-----	-------------------	---------	--------

No	No	No	No	No
----	----	----	----	----

Limited	No	No	Limited	Limited
---------	----	----	---------	---------

*Deformities in babies from mothers with Zika*



Viral diseases are a leading cause of hospitalisation and death

Antimalarial drugs market is expected to reach US\$1B in 2026 providing guidance to potential market size

**Vaccine development potentially can exacerbate symptoms from infections by different strains**

# 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
  - possible non-dilutive funding to support clinical studies.



# BOARD AND CORPORATE SNAPSHOT



**Dr Paul MacLeman**  
Executive Chairman

Dr Paul MacLeman brings decades of experience across the life sciences sector, including veterinary practice, pharmaceutical development and manufacturing, biotechnology, diagnostics and finance.



**Dr David Foster**  
Managing Director

Dr Foster has 25+ years experience in life sciences representing pharmaceutical, biotherapeutic and diagnostic companies, while in private legal practice. He has co-founded a number of biotechnology companies as well as BioNTX, a regional life science trade association.



**Dr David Brookes**  
Non-Executive Director

Dr David Brookes has extensive experience in the health and biotechnology industries, first becoming involved in the biotechnology sector in the late 1990's as a consultant. Dr. Brookes has since held Board positions in a number of ASX listed biotechnology companies, including as Chairman of genomics solutions company, RHS Ltd.



**Mr Albert Hansen**  
Non-Executive Director

Mr Al Hansen is the Managing Partner. KESA Partners. He brings decades of experience in healthcare and investment, including Managing Director of Signet Healthcare Partners, serving on investee companies as Chairman, Director and Interim CEO of pharmaceutical companies and CROs.



**Dr Anna Lavelle**  
Non-Executive Director

Dr Lavelle is Chair of Medicines Australia; previously CEO and Executive Director of AusBiotech Ltd. and the Australian Red Cross. Director, Research Australia, the Agricultural Biotechnology Council of Australia and the Advisory Board for the School of Biological Sciences at Monash University.



## Corporate snapshot Key data points

<b>\$0.06</b> Share Price (AUD) (As at 16 April 2024)	<b>\$6.83m</b> Market Cap (As at 16 April 2024)
<b>113,796,642</b> Ordinary shares on issue (As at 16 April 2024)	<b>A\$1.00m</b> Cash (As at 31 Dec 2023)
<b>32,507,388</b> Options with Piggy Back Right.  <u>ILAO Option terms:</u> Exercise price \$0.06 expire 14 March 2025	<b>Piggy Back Right:</b> Options required to be exercised prior to 14 June 2024. One further option (ILAO) will be issued on same terms

# OTHER KEY TEAM MEMBERS



**Bobbi Drais**

Senior Regulatory Consultant

Bobbi is a dynamic global leader with an impressive track record spanning over 25 years in regulatory affairs, specialising in regulatory strategic management in biologics, Advanced Therapy Medicinal Products, Prescription and OTC Drugs, Medical Devices and Cosmetics. She was also a former senior executive serving as member of multiple executive leadership teams with extensive experience in designing, developing and leading global regulatory teams.

She has proven success in the development of regulatory strategy to support optimal progress of projects from product development through to initial approval as well as geographical roll-out and post-market compliance activities.



**Nick McCoy**

Vice President Clinical Product Development

Nick is an experienced clinical research professional with a demonstrated history working in the pharmaceutical, biotechnology and medical device industries. His experience spans multiple therapeutic areas and all phases of clinical research. He has held positions within large global organizations and smaller privately held companies, and has considerable experience managing and overseeing global clinical teams and clinical trials in numerous countries.

Nick holds a Bachelor's degree in biology from Southern Nazarene University and a Masters certificate in Clinical Research Administration from George Washington University. He also completed a post-graduate course in clinical pharmacology, drug development and regulations through Tufts University.

# SCIENTIFIC ADVISORY SLIDE



**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.)



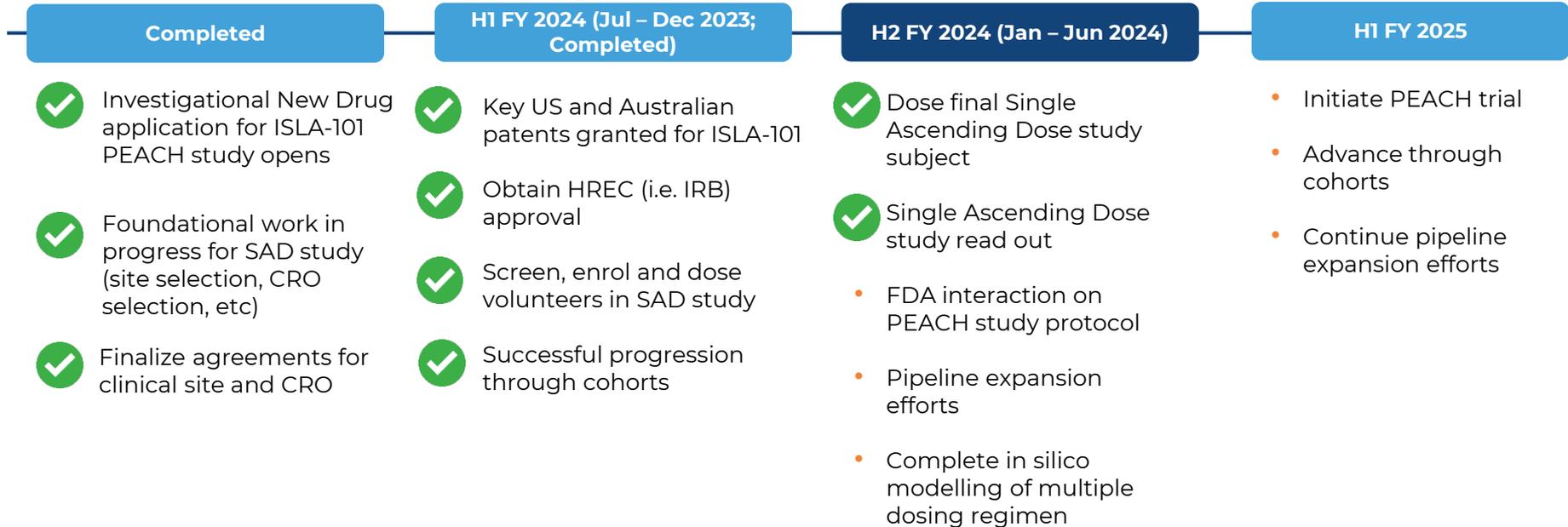
**Dr Amy Patick**

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



\* PEACH: Phase 2a, randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model.

# Island Pharmaceuticals (ASX: ILA)



[islandpharmaceuticals.com](https://islandpharmaceuticals.com)



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



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

