



**ISLAND**

PHARMACEUTICALS

Antiviral therapeutics

# SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA) | February 2024

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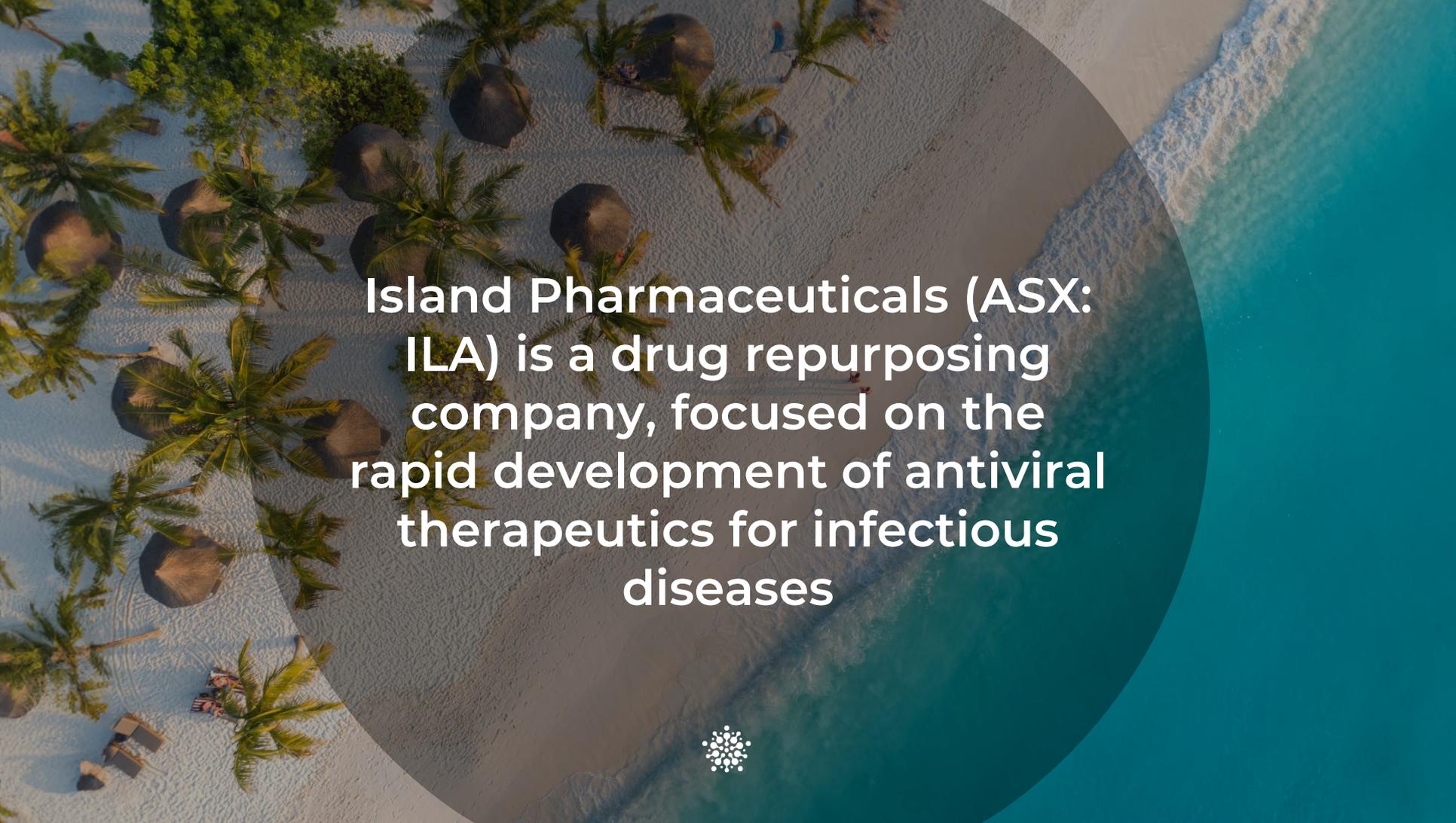
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An aerial photograph of a tropical beach with white sand, palm trees, and turquoise water. A large, semi-transparent circular graphic is overlaid on the right side of the image, containing white text. At the bottom center of the circle is a small white 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.



Advancing Single  
Ascending Dose study



Priority Review  
Voucher potential



Pipeline expansion  
underway

Dosing complete, study **on track to report final data** in early 2024.

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*

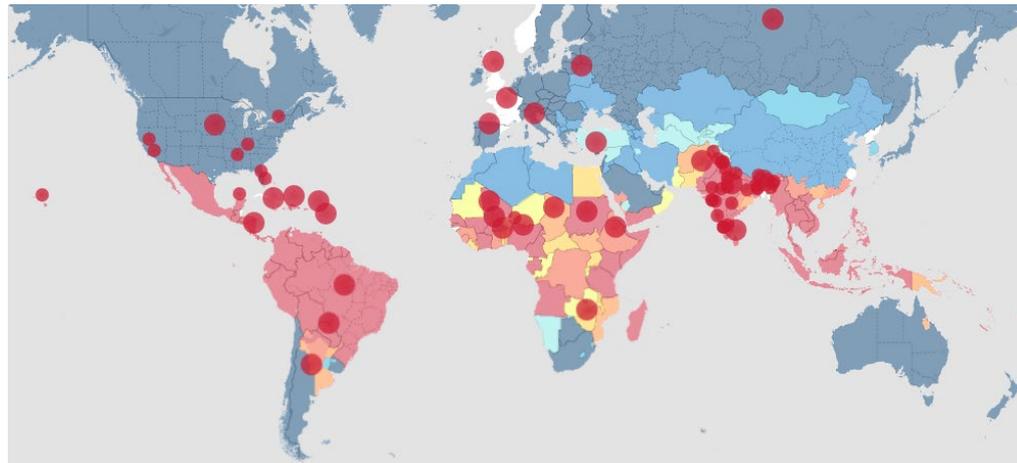


# DENGUE IS A WIDESPREAD ISSUE



**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 January 11, 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**

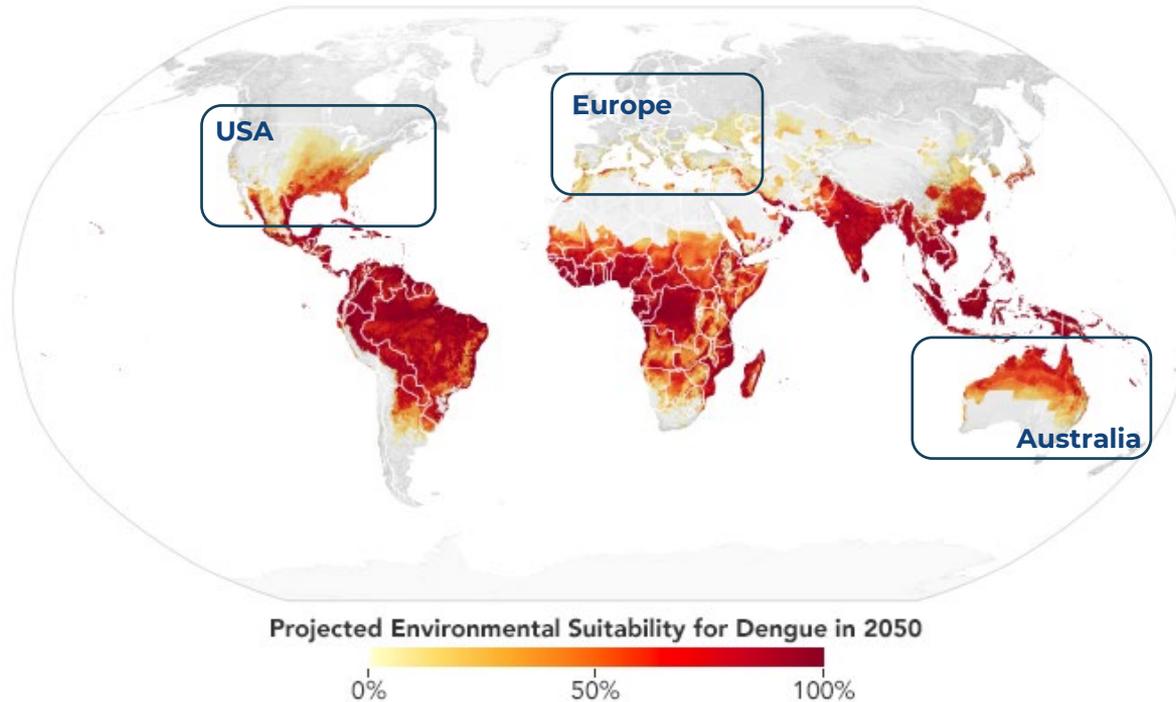
**Dengue cases reach 647 in Barbados**

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>



**“Dengue fever will  
become a major threat in  
the southern US, southern  
Europe and new parts of  
Africa this decade”**

*World Health Organisation, 6 October 2023*



# 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



# ISLA-101 BROAD ACTIVITY EVIDENT



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

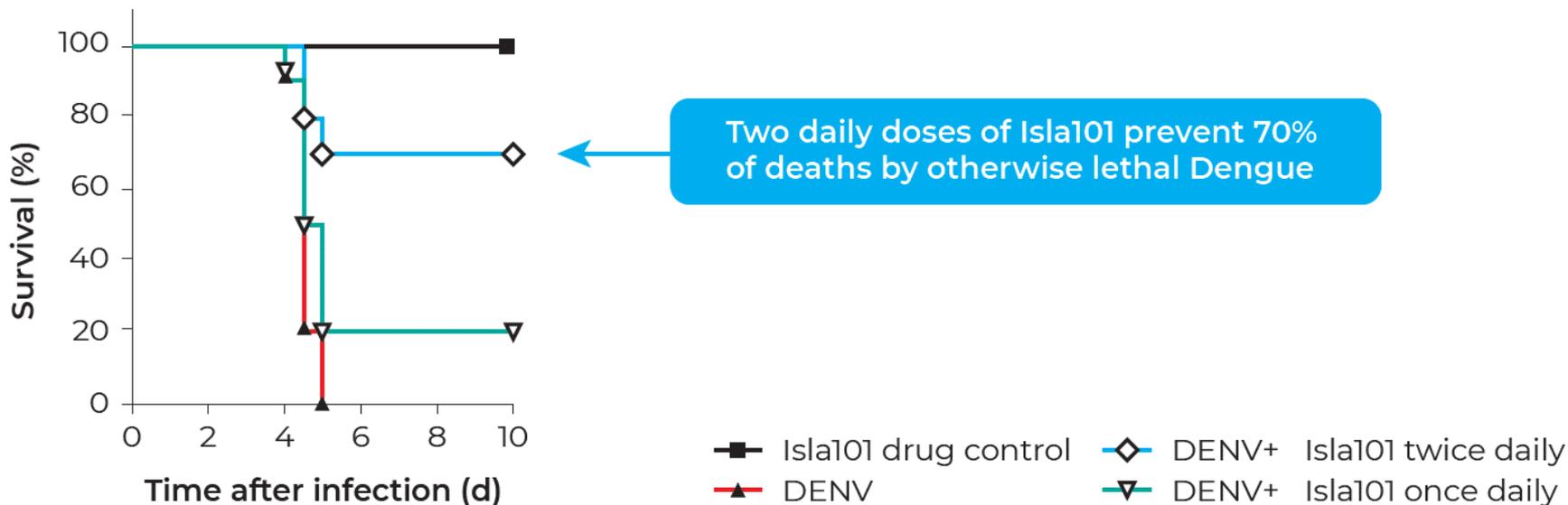


- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated broad anti-viral activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown to prevent death in 70% of subjects
- Increasing concentrations of ISLA-101 prevent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

# PREVENTS ANIMAL DEATHS FROM LETHAL DENGUE

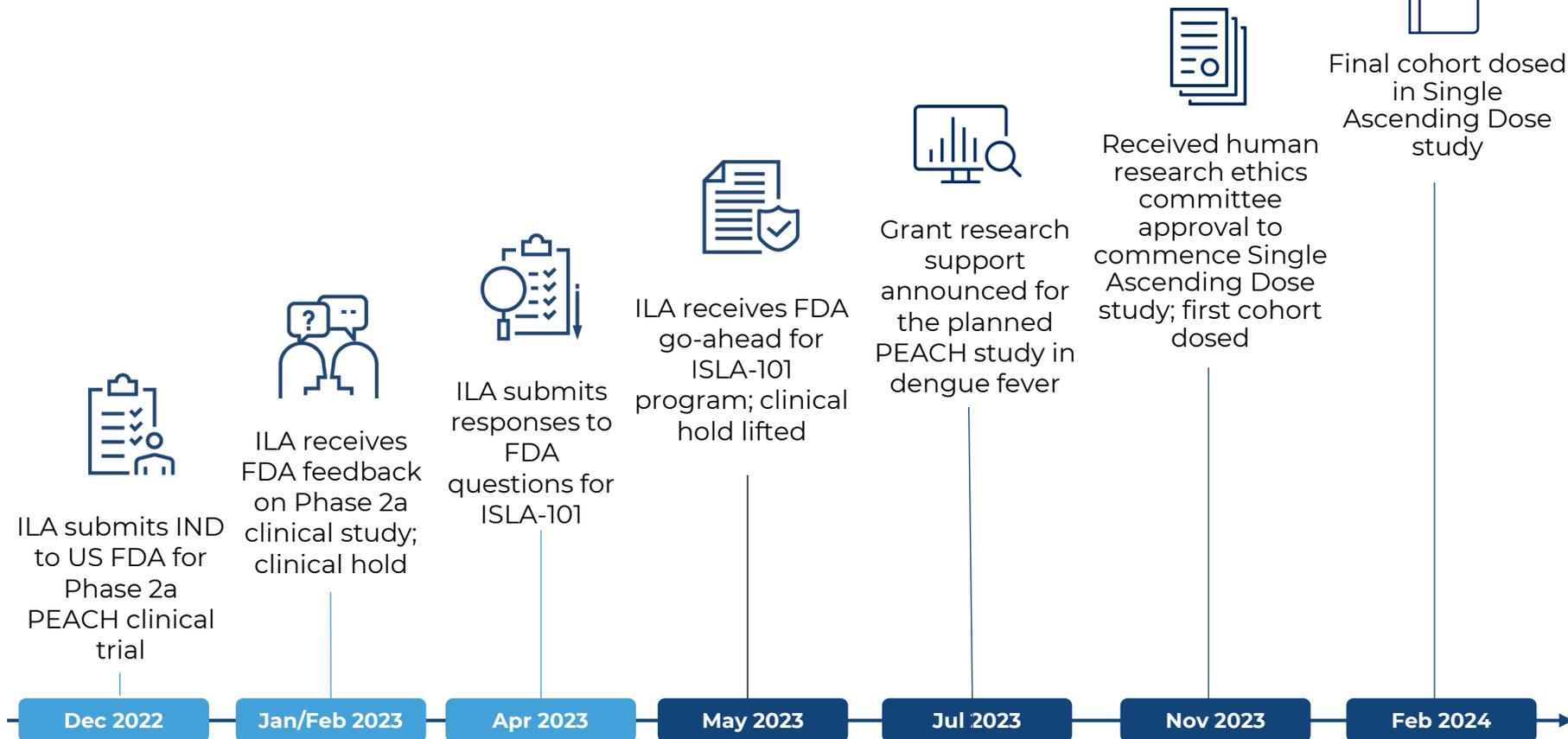


ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.



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

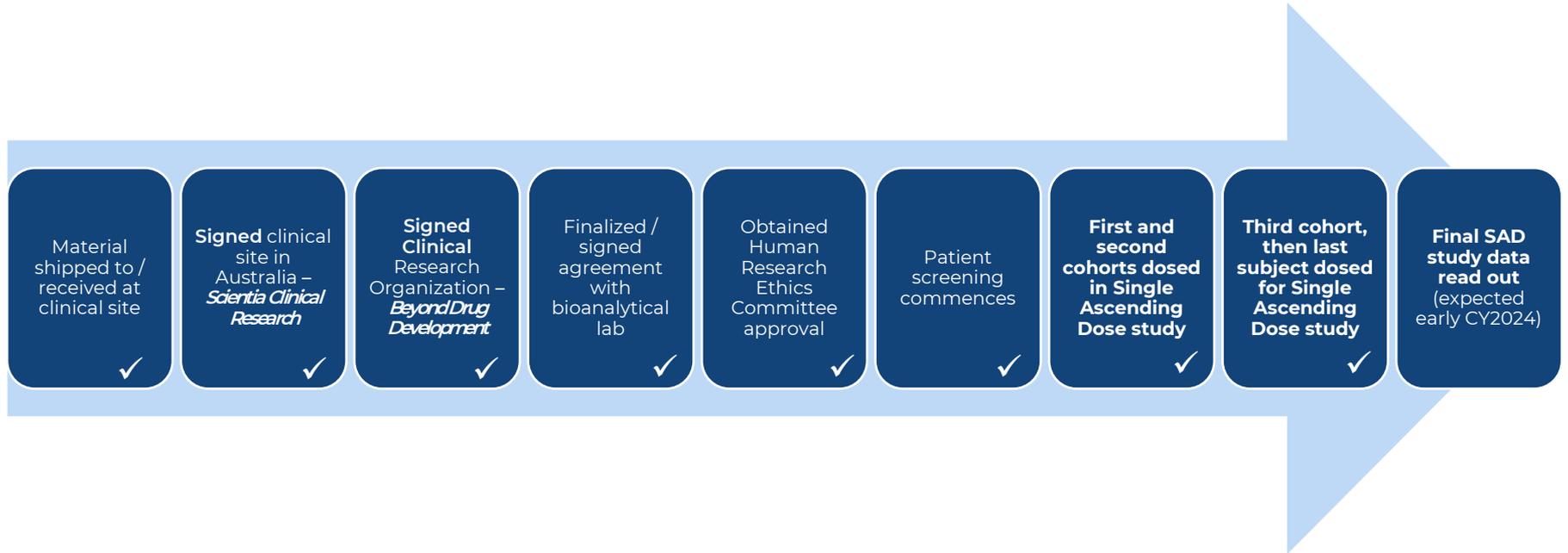
# RECENT ISLA-101 PROGRESS



# SINGLE ASCENDING DOSE STUDY – KEY ACTIVITIES



Several workstreams are underway, providing support for commencing the Single Ascending Dose study



# SINGLE ASCENDING DOSE STUDY PROTOCOL



The aim of the study is to ensure that increasing doses of ISLA-101 are safe and well tolerated, and that administered doses could safely achieve blood concentrations that are predicted to be effective against the dengue virus.

<b>Inclusion</b> 	<b>Exclusion</b> 	<b>Dosing</b>
<ul style="list-style-type: none"><li>• 4 cohorts of 8 healthy subjects</li><li>• Age 18-65</li><li>• Willing to use contraception for the duration of the study</li><li>• Informed consent</li></ul>	<ul style="list-style-type: none"><li>• Female: pregnant or lactating</li><li>• Prior infection with HIV, HCV, Flaviviruses</li><li>• Current, or a history of, auto-immune disease</li></ul>	<ul style="list-style-type: none"><li>• Doses are 300, 600, and 900 mg/m<sup>2</sup>, under fasted conditions. The Safety Review Committee will recommend a cohort to repeat the dosing under fed conditions.</li><li>• 5 day stay in the clinical research unit followed by a final safety follow-up visit at Day 8.</li><li>• After each cohort, a Safety Review Committee will review safety data and determine if it is safe to move to the higher dose.</li></ul>

**The study is expected to be short. Dosing commenced in late 2023 and remains on track to read out in early 2024. It is being run in Australia, enabling access to the Australian Federal Government's R&D tax incentive.**

# STUDY PARTNERS



Scientia Clinical Research is an FDA audited, early phase clinical trials facility, with world-class clinical trial expertise and state of the art facilities.

Scientia is the clinical site for the ISLA-101 Single Ascending Dose, dose escalation study.

Beyond is a leading Contract Research Organisation (CRO) based in Brisbane, Australia, with a focus on product development and early phase research.

Beyond brings extensive industry experience, through its expert team (averaging 20 years' experience) and strong reputation in serving early to mid-stage biotech companies and established pharmaceutical companies.

# ISLA-101 DEVELOPMENT MILESTONES



- Island expects to have final data from the Single Ascending Dose study for ISLA-101 in early CY2024
- The company plans to seek a meeting 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

# PHASE II DENGUE (PEACH) TRIAL STUDY



“PEACH” study- A Phase 2a, Randomized, Double blind, Placebo-controlled Study for the **P**rophylactic **E**xamination of an **A**ntiviral in a Dengue **C**hallenge Model

## Phase II trial protocol

Up to 4 cohorts/4 arms

### Inclusion

- Healthy subjects
- Age 18-65
- Willing to use contraception for the duration of the study
- Informed consent

### Exclusion

- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

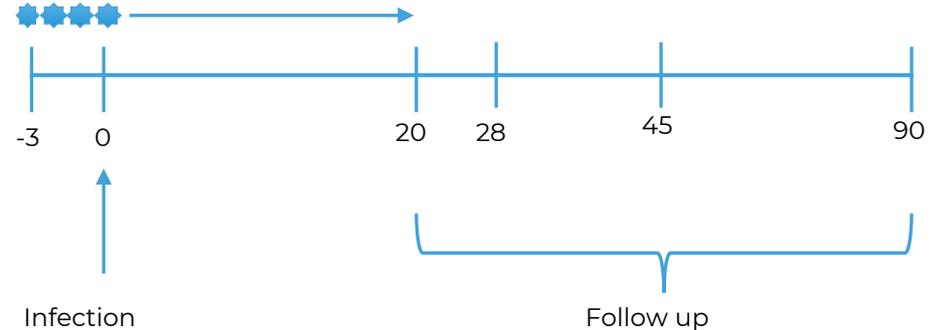
### Primary endpoint

- Assess the prophylactic effect of ISLA 101 on fever, clinical symptoms, laboratory abnormalities and viremia 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

## Administer ISLA-101 daily



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

US\$1.3m Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY will support laboratory testing and data analysis during Island's PEACH study.

# 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>\$0.088</b> Share Price (AUD) (As at 05 Feb 2024)	<b>\$7.15m</b> Market Cap (As at 05 Feb 2024)
<b>80,968,468</b> Ordinary shares on issue (As at 18 De 2023)	<b>A\$1.00m</b> Cash (As at 31 Dec 2023)

# 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.)



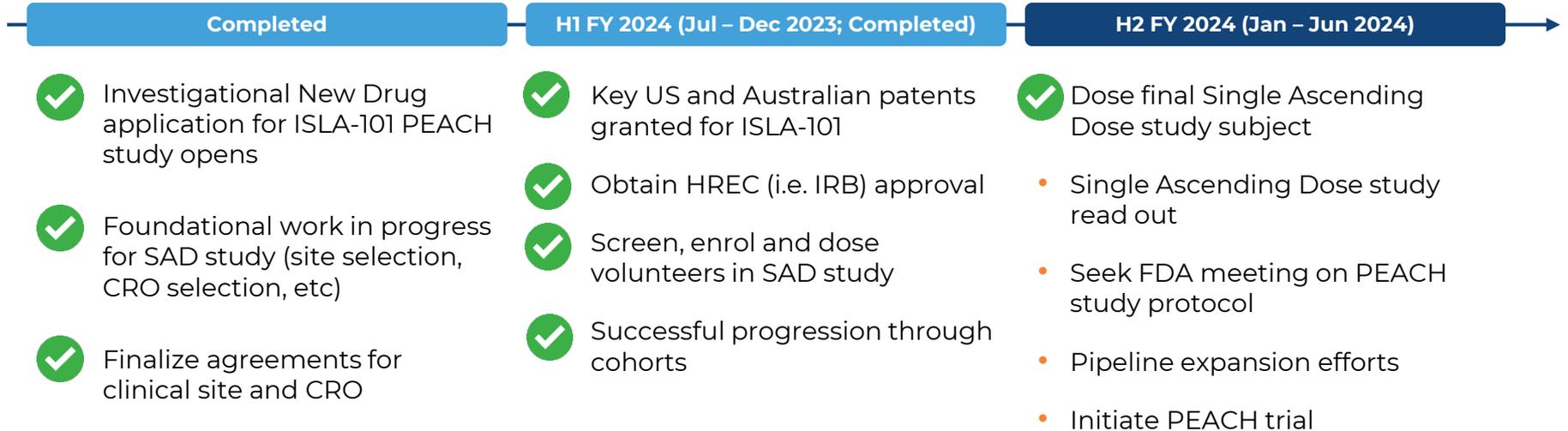
**Dr Amy Patick**

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.

# Contact

**David Foster**  
**Chief Executive Officer & Executive Director**  
**[dfoster@islandpharmaceuticals.com](mailto:dfoster@islandpharmaceuticals.com)**



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



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



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