

**5 December 2022**

## **ASX Announcement**

### **ISLA-101 trial update and investor presentation**

MELBOURNE Australia, 5 December 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; “Island”; “the Company”) is pleased to provide a brief progress update on its ISLA-101 Phase 2a PEACH<sup>1</sup> human clinical trial, and to share a copy of the presentation being delivered to investors in meetings through December 2022.

Following the recent news (ASX announcements: 14 November 2022 and 28 October 2022) that clinical drug product had been manufactured for the Company's ISLA-101 Phase II clinical trial in dengue fever, Island has now made its Institutional Review Board submission, which is analogous to an application for Human Research Ethics Committee (HREC) approval. This is an important regulatory requirement ahead of trial commencement.

CEO of Island Pharmaceuticals, Dr David Foster said, *“We are excited by the pace with which our trial preparation is now moving and look forward to keeping the market updated as we make further progress in the coming weeks.”*

*Investors can expect updates on the final results of our clinical drug product stability and ethics committee submission. We are also in the final stages of preparing our Investigational New Drug application for submission to the US FDA.”*

A copy of the presentation being delivered to investors through meetings in December 2022 is attached.

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

Dr Paul MacLeman  
Executive Chairman  
Island Pharmaceuticals Ltd  
[info@islandpharmaceuticals.com](mailto:info@islandpharmaceuticals.com)

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<sup>1</sup> The PEACH study is a Phase 2a Randomized, Double Blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model.



## About Island Pharmaceuticals

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Island (ASX: ILA) is a mid-clinical-stage drug repurposing company, focused on the topical area of antiviral therapeutics for 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. The Company is close to commencing a Phase 2a clinical trial in dengue-infected subjects.

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

# SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA)  
Spark Plus

December 2022

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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

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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.

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



# ISLAND AT A GLANCE



## Advancing lead drug

ISLA-101 toward Phase 2  
“PEACH”\* clinical trial for the  
prevention of dengue fever.



## Dengue infects +390 million year

No current pharmaceutical treatment  
for the disease. Limited access to only  
one vaccine.



## Major market potential

In mosquito-borne  
diseases, exacerbated by  
climate change.



## Positive results in aggressive models

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



## Priority Review Voucher potential

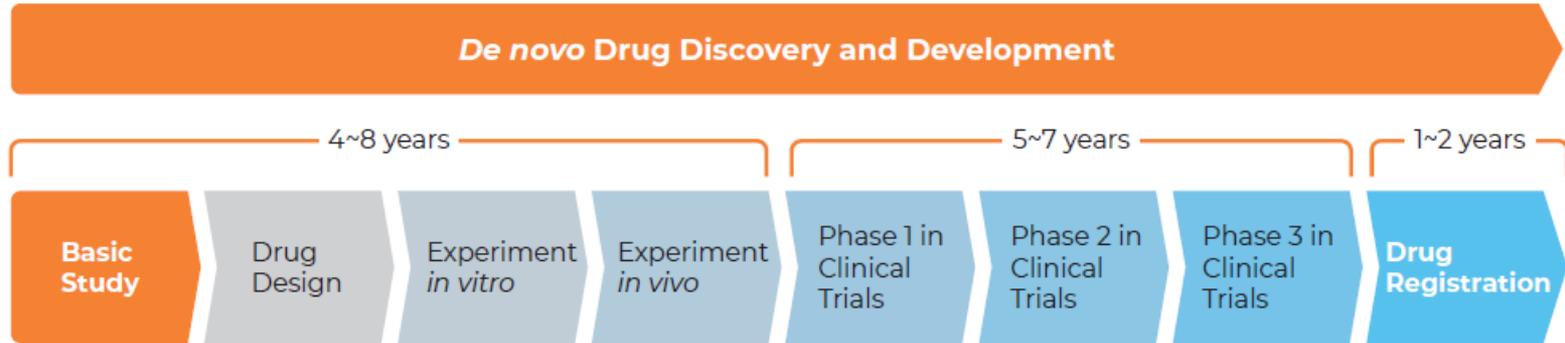
For ISLA-101 at the time of FDA approval.  
Last ten PRVs sold for an average of  
US~\$110M.



## Pipeline expansion underway

Targeting other viruses with  
significant unmet need and  
limited competition.

# THE BENEFITS OF DRUG REPURPOSING



**De novo Drug Discovery and Development**

- Low Success Rate
- Huge Cost and Time-consuming Development

**Drug Repurposing**

- Known Drug Safety
- Reduced Pharmacokinetic Uncertainty



Reduced time, cost and risk

# THE CHALLENGE



**“DENGUE FEVER IS THE MOST RAPIDLY  
SPREADING MOSQUITO-BORNE VIRUS  
INFECTION IN THE WORLD.”**

World Health Organisation, 13 October 2022



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# MOSQUITO BORNE VIRUSES: GLOBAL CHALLENGES



Nov 23, 2021

Upcoming mosquito season may be the worst yet. Here's how to prepare yourself

Australians are facing a brutal mosquito season bolstered by recent wet weather



Chikungunya, Zika, and Dengue virus incidence in Mexico may be higher than previously reported

Dec 1, 2021



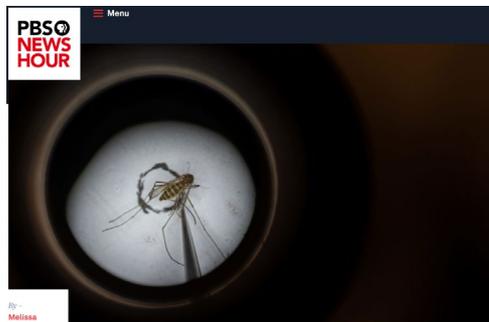
The researchers found 2.4 times the rate of arbovirosis as originally reported, including coinfections, suggesting underestimation of the incidence of the three viruses. However, future research is needed to provide up-to-date incidence estimates of each virus.



Singapore is facing a dengue fever 'emergency' and peak season has only just begun

By Annika Burgess and Joshua Boscaini

Posted 11h ago, updated 10h ago



By Melissa Bailey, Kaiser Health News

Leave your feedback

Share

Altered by climate change, the U.S. could become ideal for West Nile to thrive



Here's what we know about the Japanese encephalitis outbreak in Victoria, South Australia, NSW and Queensland

By Freya Michie and Siân Johnson

Posted Wed 9 Mar 2022 at 1:52pm, updated Wed 9 Mar 2022 at 5:41pm



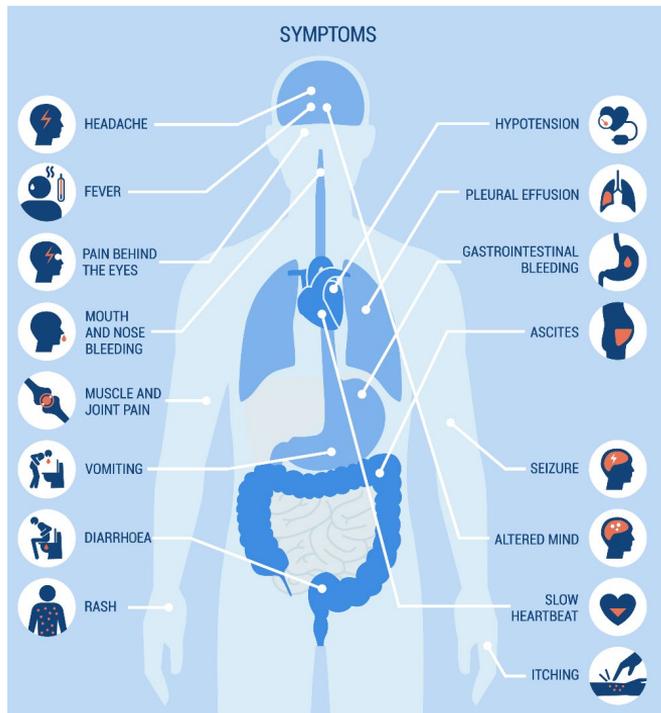
In temperate Nepal, climate change paves way for tropical dengue fever

by Abhaya Raj Joshi on 31 October 2022



# WHY DENGUE AS A FIRST TARGET FOR ISLA-101?

SIGNIFICANT UNMET NEED FOR DISEASE WITH INCREASING INCIDENCE



Significant unmet need (3.9 billion people at risk)

Increasing spread to US, EU and Australia

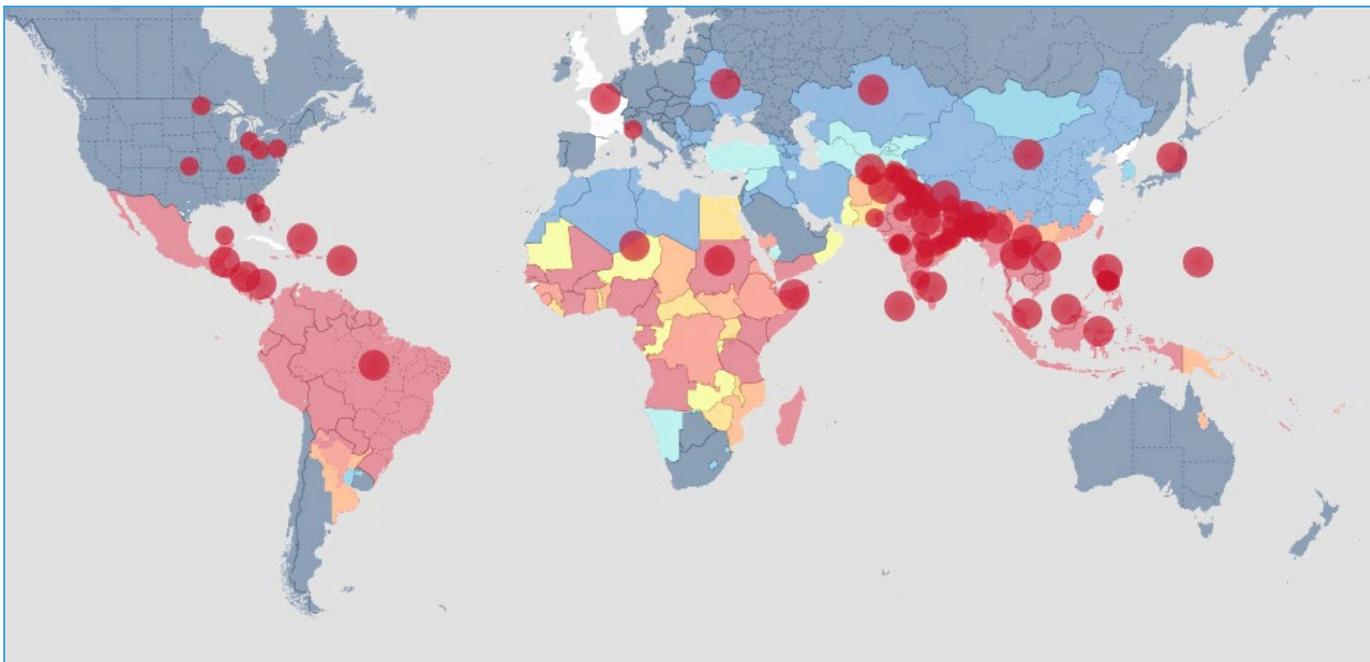
ISLA-101 has both therapeutic and prophylactic potential

Strong animal and human model results

First claim then springboard into other arboviruses

Priority Review Voucher eligibility

# DENGUE IS A WIDESPREAD ISSUE



## HealthMap Reports

Recent reports of local or imported dengue cases from official, newspaper, and other media sources.

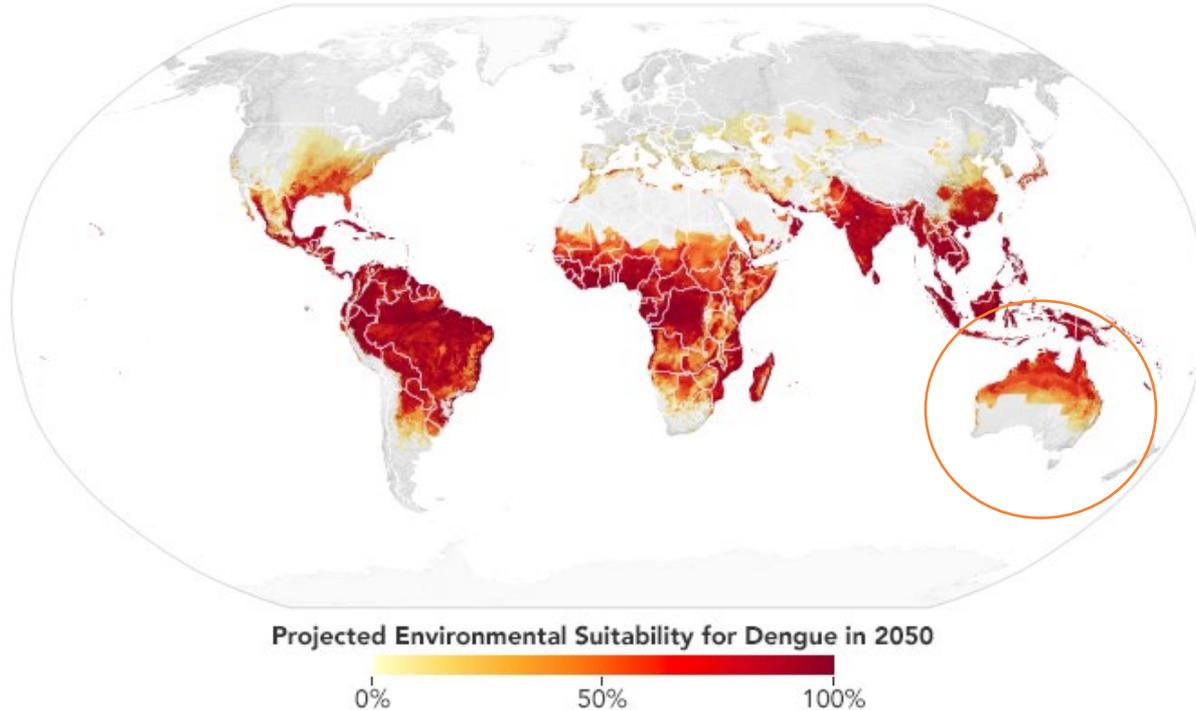
Source.

● Country Level ● Local Level



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

# 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.)



ISLA-101



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# ISLA-101 REPURPOSED DRUG

DRAMATICALLY REDUCES DEVELOPMENT TIME, RISK AND COST



**ISLA-101,  
originally a  
cancer drug**

Originally identified by Johnson & Johnson and studied as a potential chemotherapy



**Demonstrated  
as safe in  
humans**

Used in 45 clinical studies (including Phase II & III) demonstrating an excellent safety profile in thousands of patients including children



**Strong regulatory  
history and  
acceptance**

Multiple regulatory jurisdictions have reviewed ISLA-101 as having a well established safety profile



**Speed to market  
& early revenue  
potential**

Clearance of early phases allows many years to be saved in drug development and quick path to market

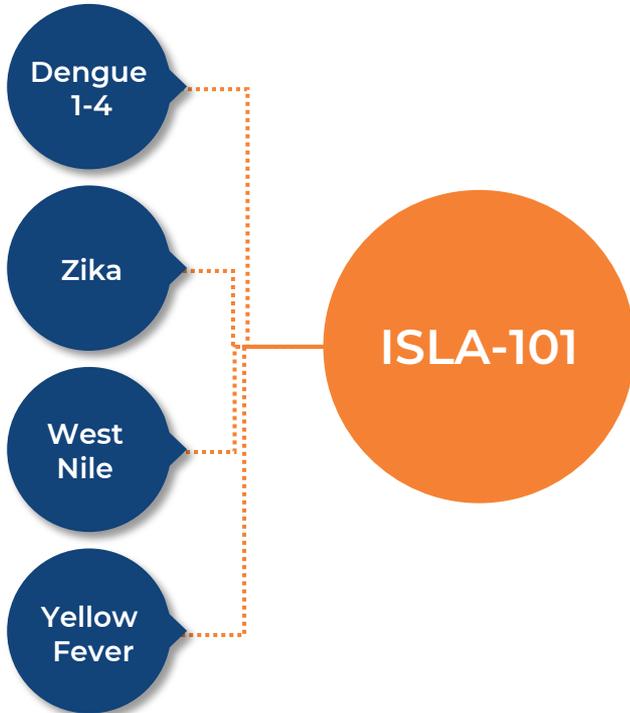


**Capitalising on  
millions spent**

Funds and time spent to date reduce risk and allow for immediate move to Phase II study

# ISLA-101 BROAD ACTIVITY EVIDENT

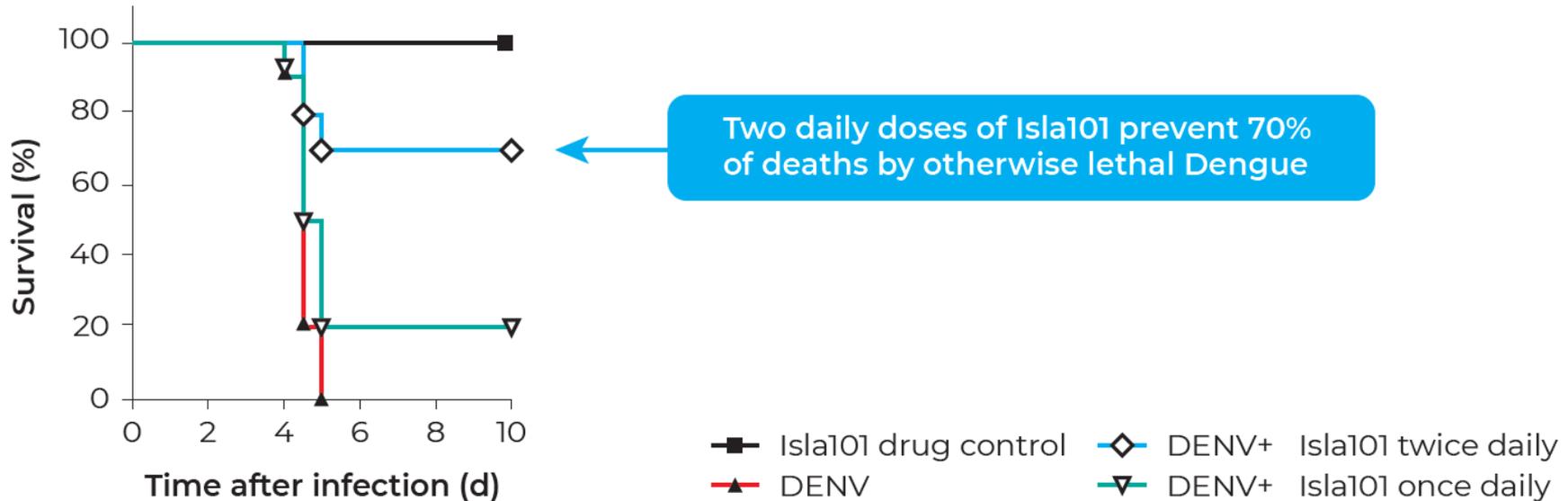
DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES (A SUBGROUP OF ARBOVIRUSES) IN MULTIPLE MODELS OF INFECTION



- 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

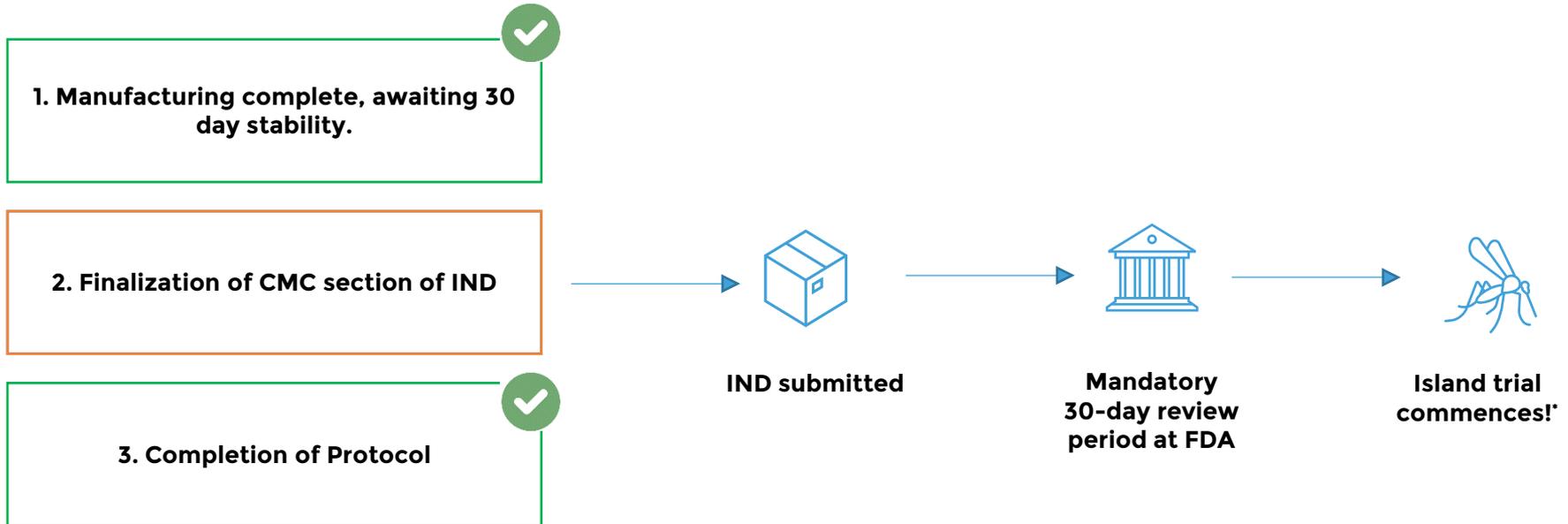
ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.



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

# PATHWAY / TIMING TO CLINICAL TRIALS

MULTIPLE WORKSTREAMS WILL TAKE US TO FDA REVIEW OF OUR IND



# MANUFACTURING PROGRESS



Manufactured capsules  
being processed



Packaged bottles  
awaiting stability  
results

# PHASE II DENGUE (PEACH) TRIAL STUDY IN DETAIL

“PEACH” STUDY- A PHASE 2A, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY FOR THE PROPHYLACTIC EXAMINATION OF AN ANTIVIRAL IN A DENGUE CHALLENGE MODEL

## Phase II trial protocol

Up to 4 cohorts/4 arms

### Inclusion

- Healthy subjects
- Age 18-45
- Willing to use contraception for the duration of the study
- Informed consent

### Exclusion

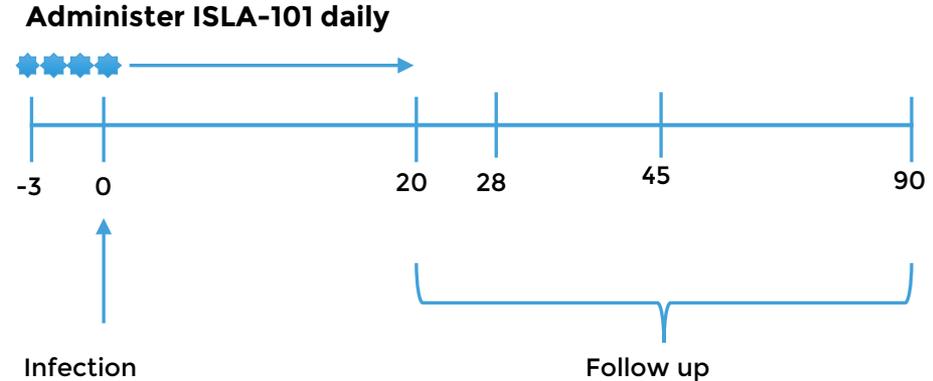
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

### 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

- Characterise 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



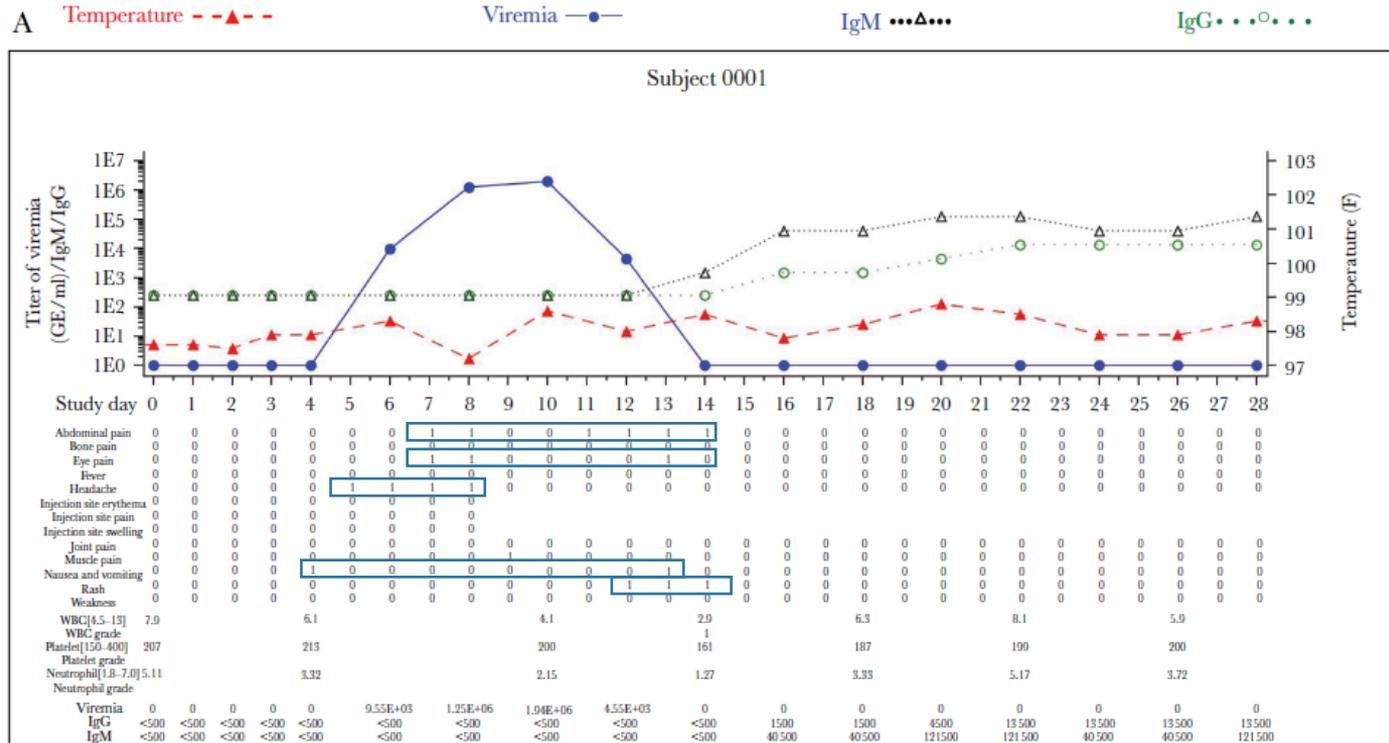
The study will be run at SUNY Upstate Medical University Syracuse, New York

# PHASE 1 CONTROL DATA DEMONSTRATES BENEFIT OF CHALLENGE STUDY APPROACH

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

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

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



Endy et al, J Inf Dis 2021



# THE COMMERCIAL OPPORTUNITY



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# COMMERCIAL OPPORTUNITY



Prophylactic for  
travelers



Military



National  
outbreaks



Government  
Stockpiles



Priority Review  
Voucher



## Tropical area travellers opportunity:

- Comparable to malaria market - expected to reach US\$1B in 2026\*
- Increasing numbers of countries due to global warming

## Military opportunity:

- Isla is partnering with army (CRADA in place) for Phase 2a clinical trial in Dengue Fever
- We will pursue a contract with the military as we get closer to approval

## Endemic area opportunity:

- Many millions of patients in Central and South America
- Potential for sales for disease suppression and treatment during outbreaks
- Potential for endemic countries to establish and maintain drug stockpiles as happens with influenza

# ADVANCING OUR PIPELINE

## Viruses to target prioritised by:

Medical relevance for the Americas, Europe, Australia/NZ

Significant unmet need

Limited competition

Insight into virus mechanism/life cycle

## Exemplary viruses that met these criteria include:

- Zika virus
- Human respiratory syncytial virus
- Human rhinovirus
- Echovirus
- Human adenovirus
- Human cytomegalovirus
- Coxsackievirus
- Hepatitis delta virus



Under collaborations with Monash and Griffith Universities, Island is further evaluating next viruses to investigate.

# UPCOMING MILESTONES

**H1 FY 2022**

(July-Dec 2021)

- ✓ Sign SUNY CTA
- ✓ Announce Principal Investigator
- ✓ Engaged CRO
- ✓ Drug substance (API) manufactured
- ✓ Advance research collaboration

**H2 FY 2022**

(Jan-June 2022)

- ✓ New drug product manufacturer secured
- ✓ Analytical method development
- ✓ Advancing IND

**H1 FY 2023**

(July-Dec 2022)

- ✓ Clinical material manufactured
- Clinical material released and shipped to site
- Finalize and File IND
- ✓ File IRB

**H2 FY 2023**

(Jan-June 2023)

- Open IND
- Screening, enrolment, dosing subjects in PEACH\* trial
- Advance through PEACH cohorts
- Trial read out
- Identify lead molecules from research collaborations

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

# BOARD, MANAGEMENT & SCIENTIFIC BOARD

## BOARD & MANAGEMENT TEAM



**Dr. Paul MacLeman**  
Executive Chair



**Dr. David Foster**  
CEO & Executive Director



**Dr. Anna Lavelle**  
Non-Executive Director



**Mr. Al Hansen**  
Non-Executive Director



**Dr. David Brookes**  
Non-Executive Director

## SCIENTIFIC ADVISORY BOARD



**Teresa Byrne**  
Vice President Clinical  
Product Development



**Kevin Swiss, CMC**  
Consultant



**Assoc. Prof. Leigh Farrell**



**Prof. Stephen Thomas MD**



**Dr. Amy Patick**

# CORPORATE SNAPSHOT

## ISSUED CAPITAL\*

Total number of shares on issue 81,268,468

## MARKET CAPITALISATION

Share price (as at 2 December 2022) \$0.19

Market capitalisation \$15.44M

Cash (30 September 2022) \$3.9M

## SIGNIFICANT SHAREHOLDERS

Dr William J Garner 21,913,098 27.06%

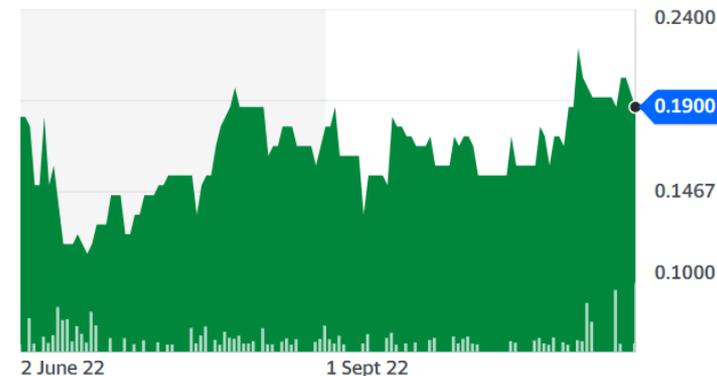
Mr Jason Carroll 10,938,466 13.46%

Mr Albert Hansen (Kesa Partners) 10,837,367 13.34%

Dr David Foster 5,282,696 6.50%

\* Data as at 2 December 2022 unless otherwise stated

## Price ILA.ASX





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**Authorized for release by Paul MacLeman, Executive Chairman**

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