



**3 November 2022**

## **ASX Announcement Island to present at ShareCafe's "Hidden Gems" investor webinar**

MELBOURNE Australia, 3 November 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to announce its participation in the ShareCafe Small Cap "Hidden Gems" Webinar, to be held Friday 4th of November 2022 from 12:30pm AEDT / 9:30am AWST.

CEO of Island Pharmaceuticals, Dr David Foster will provide an overview of the Company, which is a mid-clinical-stage drug repurposing company, focused on the topical area of antiviral therapeutics for infectious diseases.

This webinar can be viewed live via Zoom and will provide viewers the opportunity to hear from, and engage with, Island Pharmaceuticals.

### Island presentation details

**Date & time:** Friday 4 November at 12:30pm (AEDT)  
**Presenter:** Dr David Foster, CEO, Island Pharmaceuticals  
**Registration:**

To access further details of the event and to register at no cost, please copy and paste the following link into your internet browser:

[https://us02web.zoom.us/webinar/register/WN\\_1jLqCGdiSxeV-VB5ryAbNg](https://us02web.zoom.us/webinar/register/WN_1jLqCGdiSxeV-VB5ryAbNg)

A recorded copy of the webinar will be made available following the event.

- Ends -

### **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

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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)  
Investor Presentation

November 2022

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**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

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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.



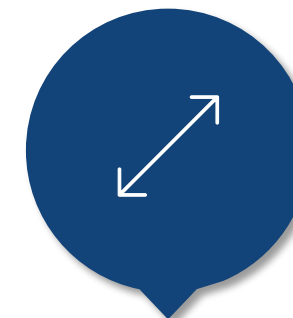
## Positive results in aggressive models

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



## Priority Review Voucher potential

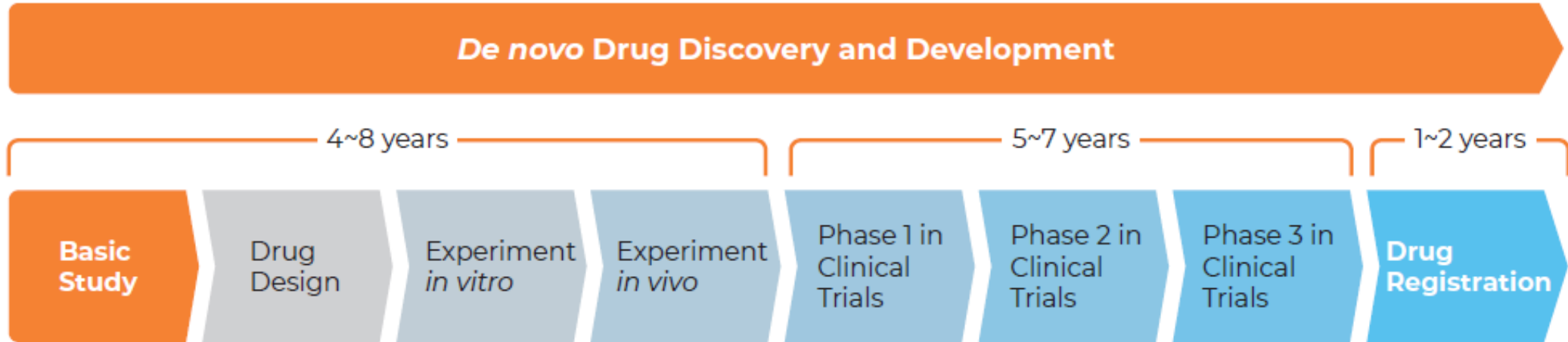
For ISLA-101 at the time of FDA approval.  
Last ten PRVs sold for an average of  
US~\$110M.



## 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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Antiviral therapeutics

# 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.



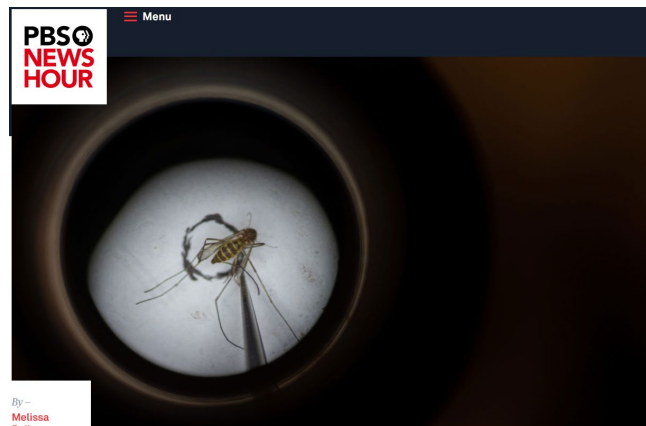
Singapore is facing a dengue fever 'emergency' and peak season has only just begun

By Annika Burgess and Joshua Boscaini  
Posted 11h ago, updated 10h ago



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

By Freya Michie and Sian Johnson  
Posted Wed 9 Mar 2022 at 1:52pm, updated Wed 9 Mar 2022 at 5:41pm



By: Melissa Bailey, Kaiser Health News

Leave your feedback

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



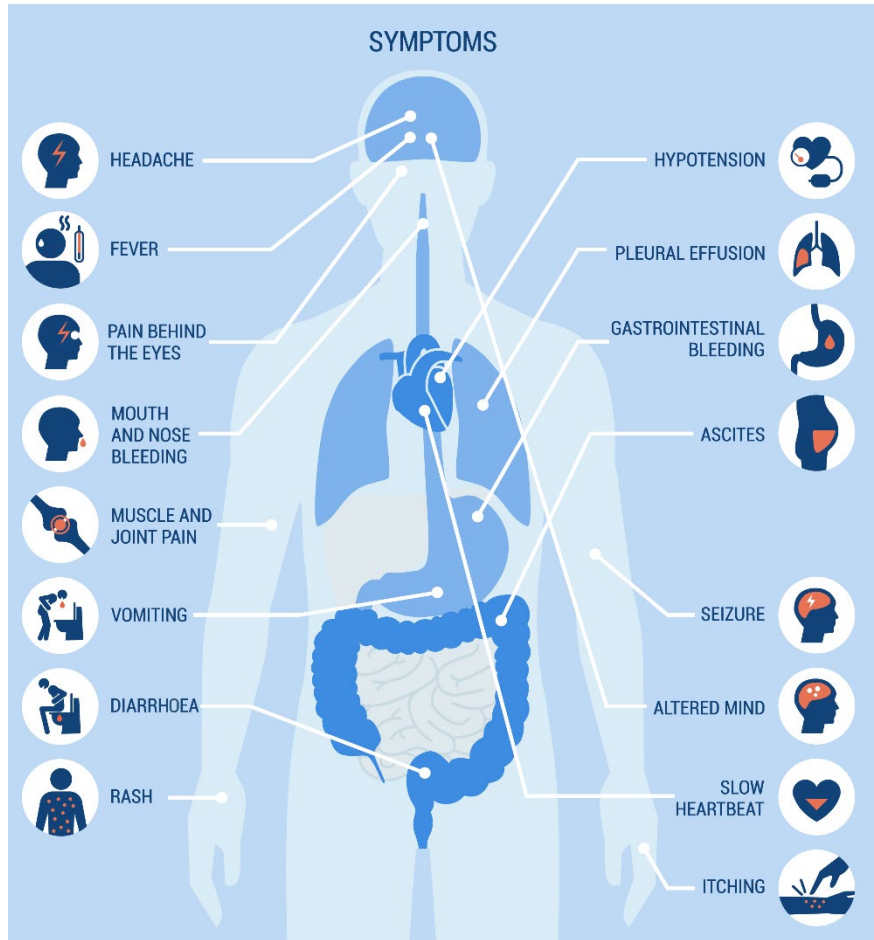
In temperate Nepal, climate change paves way for tropical dengue fever

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

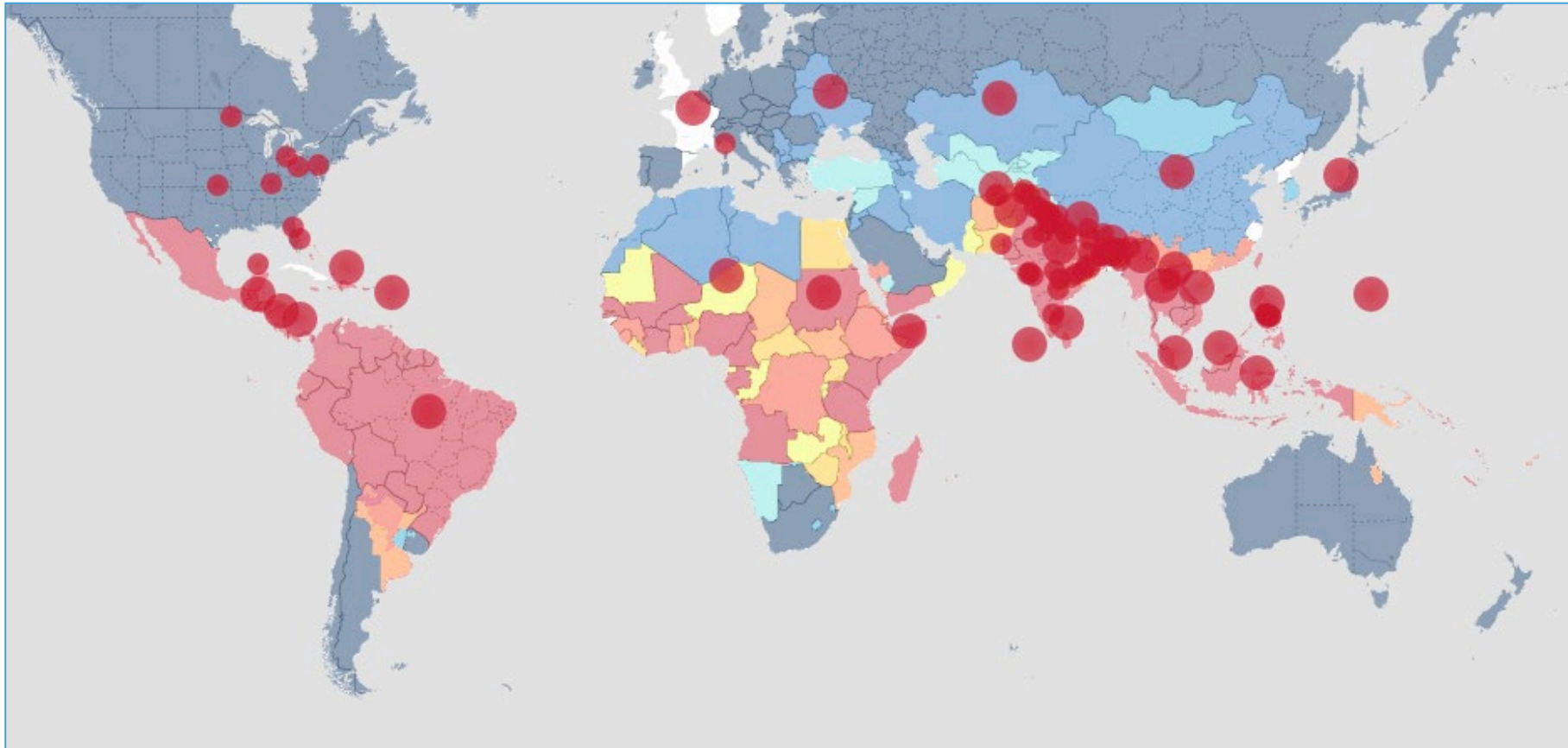
ISLA-101 has both therapeutic and prophylactic potential

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.

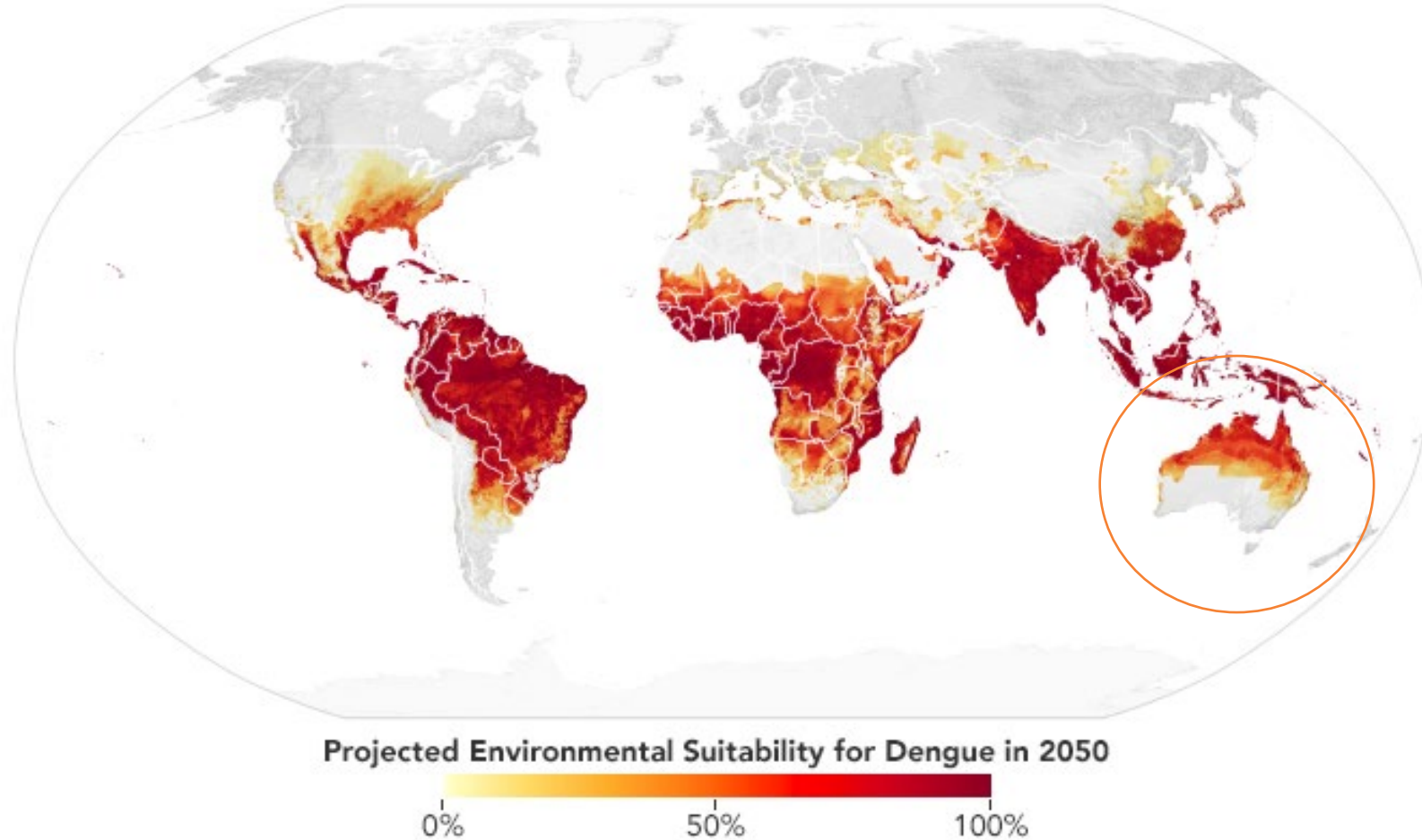
Source.

● Country Level ● Local Level

■ Absent ■ Unlikely ■ Uncertain ■ Likely ■ Present

**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.)

# LIMITED AVAILABLE SOLUTIONS

## HIGHLY PREVALENT DISEASES WITH UNMET MEDICAL NEED



**Worldwide prevalence**

Dengue fever	West Nile	Zika Virus	Yellow fever	Japanese Encephalitis
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390 million	n/a	Up to 1.5 million	130,000	70,000
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**Viral diseases are a leading cause of endemic and pandemic disease**



**Effective drug therapy**

No	No	No	No	No
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**Antimalarial drugs market is expected to reach US\$1B in 2026 providing guidance to potential market size**



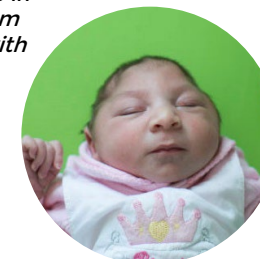
**Vaccine**

Limited	No	No	Limited	Limited
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**Vaccine development potentially can exacerbate symptoms from infections by different strains**

*Deformities in babies from mothers with Zika*



# ISLA-101



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# ISLA-101 REPURPOSED DRUG

DRAMATICALLY REDUCES DEVELOPMENT TIME, RISK AND COST



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



**Demonstrated  
as safe in humans**



**Strong regulatory  
history and  
acceptance**



**Speed to market  
& early revenue  
potential**



**Capitalising on  
millions spent**



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

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

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

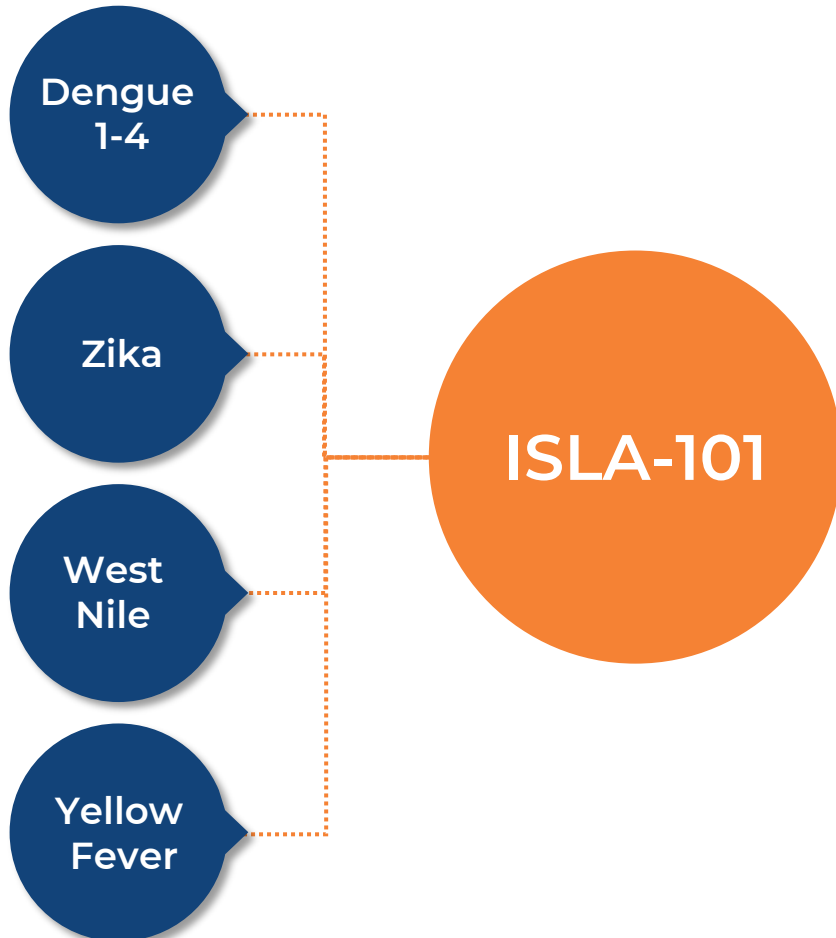
Clearance of early  
phases allows  
many years to be  
saved in drug  
development and  
quick path to  
market

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

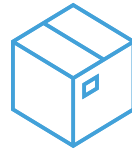
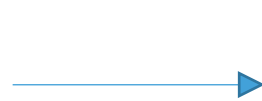
# PATHWAY / TIMING TO CLINICAL TRIALS

MULTIPLE WORKSTREAMS WILL TAKE US TO FDA REVIEW OF OUR IND

**1. Manufacturing of clinical product**

**2. Finalization of CMC section of IND**

**3. Completion of Protocol**



**IND submitted**



**Mandatory 30-day review period at FDA**



**Island trial commences!**

# MANUFACTURING PROGRESS



**Manufactured capsules being processed**



**Packaged bottles awaiting stability results**

# PHASE II DENGUE (PEACH) TRIAL STUDY IN DETAIL



Antiviral therapeutics

“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

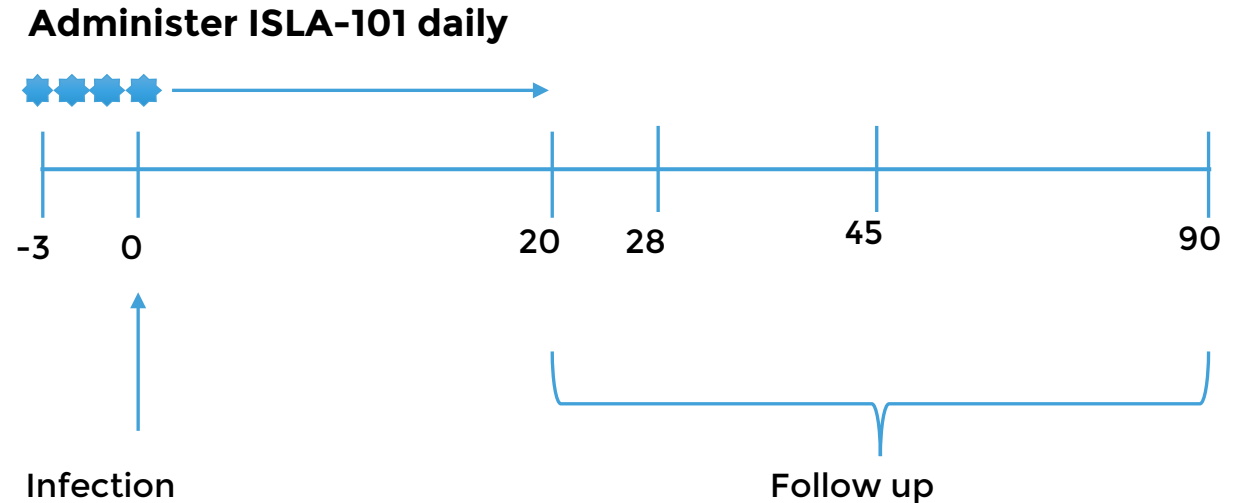
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

### 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

# THE COMMERCIAL OPPORTUNITY



# 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.



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Executive Chair



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



**Mr. Al Hansen**  
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Antiviral therapeutics

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

Authorized for release by Paul MacLeman, Executive Chairman

[www.islandpharmaceuticals.com](http://www.islandpharmaceuticals.com)  
Registered office: Suite 201, 697 Burke Rd, Camberwell VIC 3124, Australia

Island Pharmaceuticals  
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ACN 641 183 842