



**5 April 2022**

## ASX Announcement

### **Updated investor presentation and conference participation**

MELBOURNE Australia, 5 April 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to release a copy of an investor presentation that will be delivered to investors over the coming weeks.

In addition, Island announces its participation in the inaugural PAC Partners Healthcare conference which takes place in Sydney, Australia this Wednesday 6 April 2022. During his presentation, Chief Executive Officer, Dr. David Foster will discuss the coming catalysts for Island as it moves lead drug candidate, ISLA-101 toward Phase 2 clinical trials for dengue fever.

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

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Executive Chairman  
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#### **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 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, Automatic 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)

PAC Partners Inaugural Healthcare  
conference – April 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 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.

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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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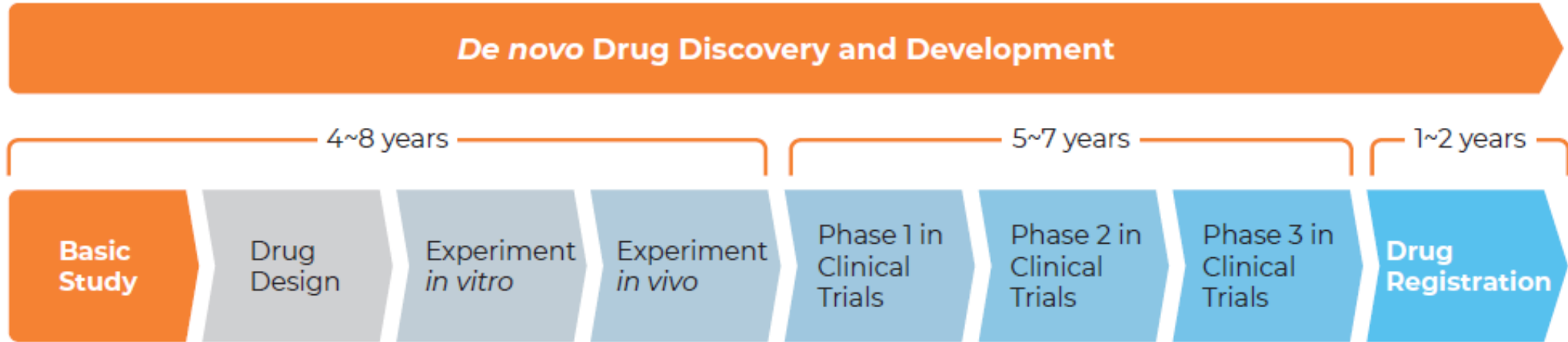
Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.

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

- Rapidly advancing lead drug ISLA-101 toward Phase 2 “PEACH”\* clinical trial for the treatment of dengue fever
- Dengue fever infects +390 million people each year. There is currently no pharmaceutical treatment for the disease and limited access to only one vaccine
- Major market potential treating mosquito-borne diseases, exacerbated by climate change
- Priority Review Voucher potential for ISLA-101 at the time of FDA approval. PRVs have recently sold for at or slightly above US\$100m
- Pipeline expansion underway, targeting other viruses with significant unmet need and limited competition.

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

# 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



# THE CHALLENGE



**ISLAND**

PHARMACEUTICALS

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.



**Insect-borne viruses like Zika and Dengue could be the cause of the next pandemic, world health chiefs warn**

- Viruses transmitted by insects could be next global pandemic WHO believes
- Pathogens like Zika virus are spread by arthropods like mosquitoes and ticks
- Nearly four billion people live in tropical and sub-tropical areas where they thrive

By **MATT POWELL FOR MAILONLINE**

PUBLISHED: 07:02 AEDT, 1 April 2022 | UPDATED: 19:59 AEDT, 1 April 2022



**BRYTFMONLINE**



**Porto Alegre issues epidemic alert for dengue, Zika virus and chikungunya at the end of the year**

**Colombia issues dengue fever alert**

by NEWS DESK

November 14, 2021



**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



**Rising dengue count a worry amid Covid**

Nov 17, 2021

*If the number of dengue cases continues to rise, complications and fatalities due to the disease are prone to occur, they opine.*

The Sydney Morning Herald

World Asia Timor-Leste

**East Timor's hospitals are fighting a deadly outbreak, but it's not COVID**



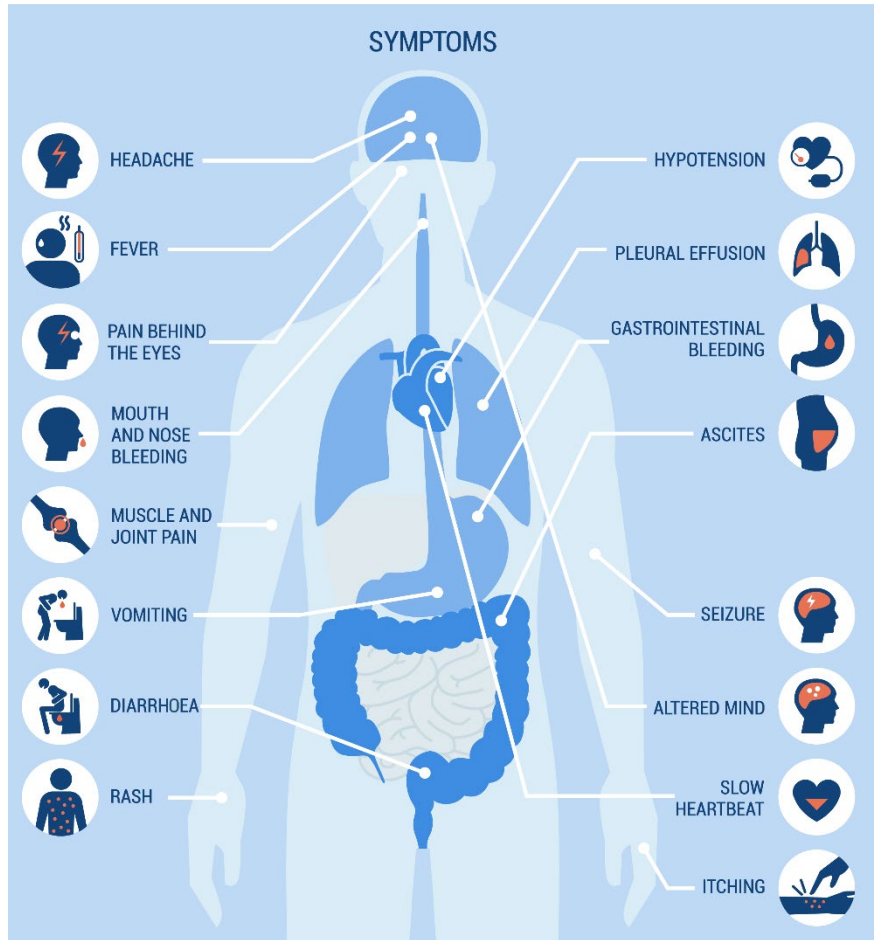
By **Chris Barrett**

February 2, 2022 – 5:33pm

Save Share A A

# 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

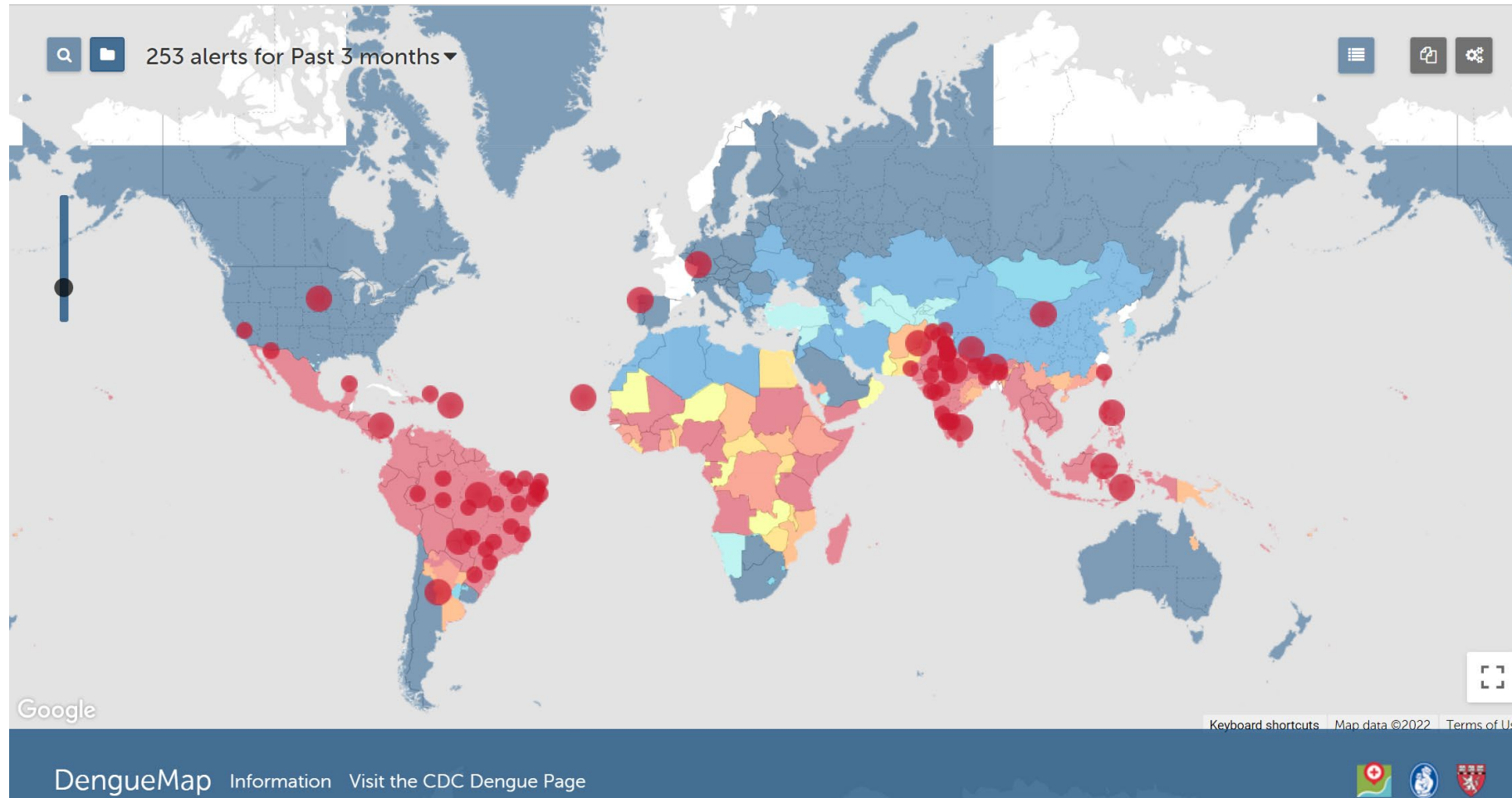
Strong animal and human model results

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.

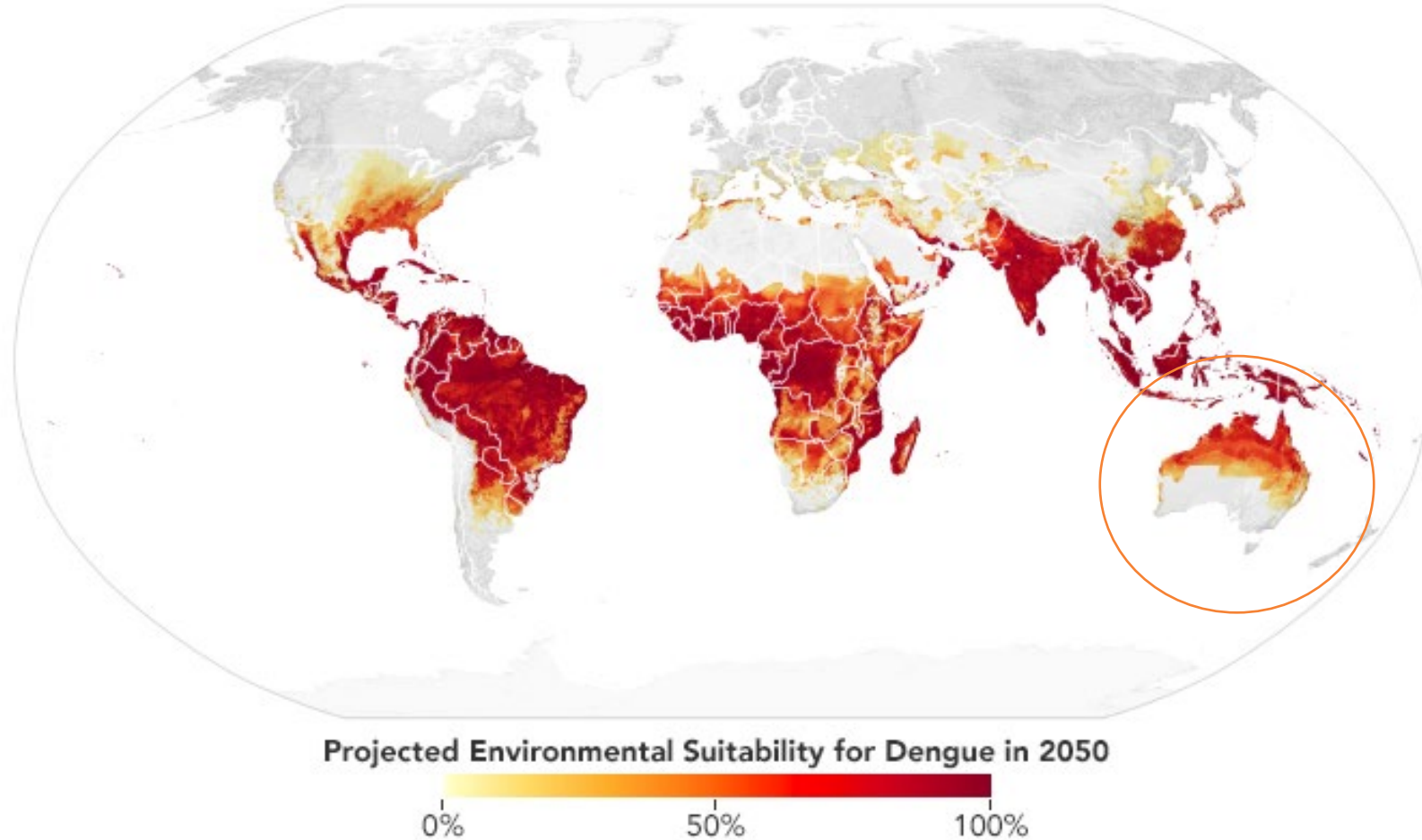
Source.

● 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



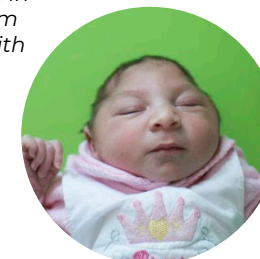
**Vaccine**

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*



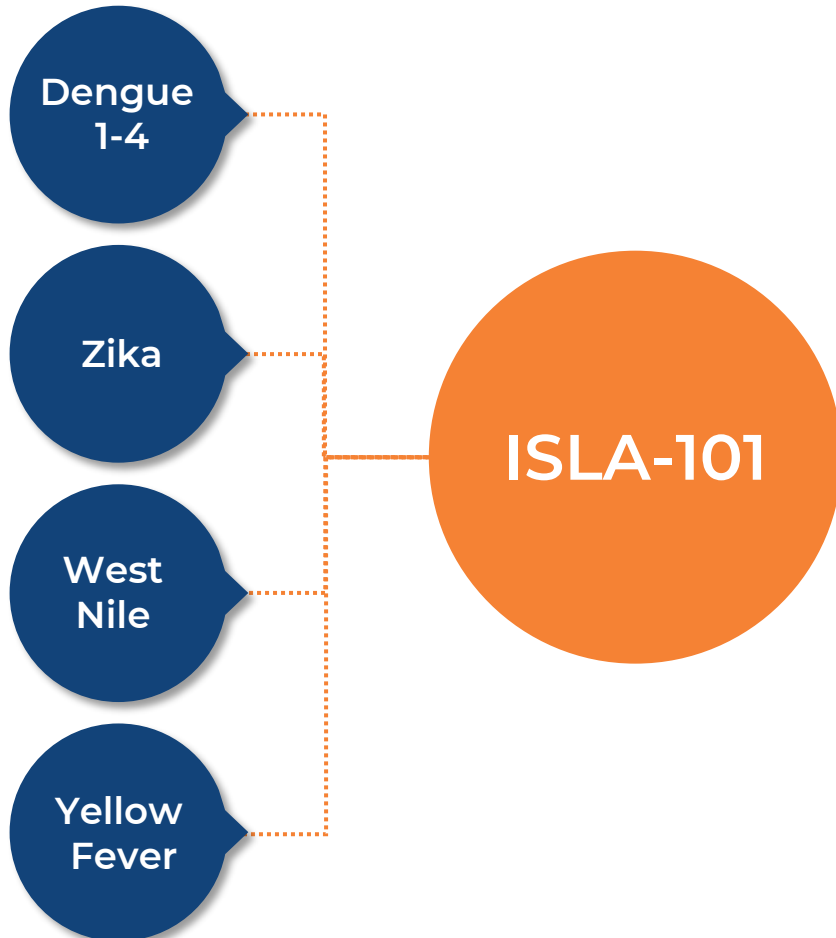
# ISLA-101



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# ISLA-101 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

# NEARING IND SUBMISSION

IND IS A CRITICAL REGULATORY MILESTONE, ENABLING PEACH STUDY COMMENCEMENT

## Sponsor information (complete)

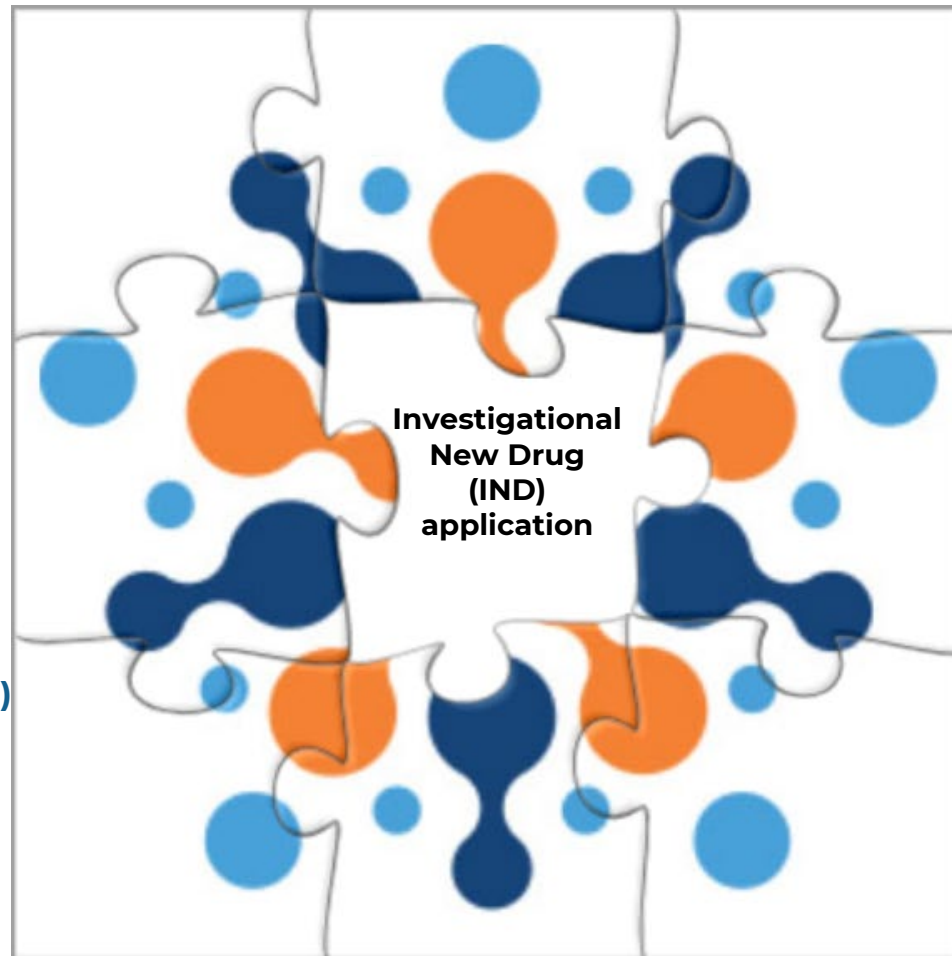
### Summary of existing human data (complete)

- ✓ ~45 previous clinical trials
- ✓ Human safety data

### Trial monitoring and biostatistics plan (complete)

### Preclinical work (complete)

- ✓ Animal pharmacology
- ✓ Toxicology
- ✓ pharmacokinetic data



## Clinical trial protocol (almost complete)

### Drug manufacturing (almost complete)

- ✓ Drug substance (API)
- Drug product

### Investigator's brochure (almost complete)

- A major body of work – includes all instructions to enable the principal investigator to run the trial

### Chemistry, manufacturing and control information (almost complete)

- ✓ Manufacturing method
- ✓ Manufacturing validation
- ✓ Drug substance manufacturing data for clinical batch
- Final clinical drug product for ISLA-101 trial manufactured

# WORLD CLASS TEAM IN PLACE

TEAM ASSEMBLED WITH DOMAIN EXPERTISE IN CLINICAL TRIALS AND MANUFACTURING

## Sponsor



Drug repurposing and dengue fever experts.

## Key Island people overseeing the ISLA-101 PEACH study



Teresa Byrne, Vice President  
Clinical Product Development.

Overseeing clinical development  
of ISLA-101 in the upcoming  
PEACH trial and other pipeline  
programs.



Larry Norder, CMC Consultant

Overseeing manufacturing of  
clinical drug substance, clinical  
drug product and formulation  
strategy. 25 years experience in  
drug development, resulting in  
several drug approvals.

## Trial site and investigator



Clinical trial protocol, oversight and experience.  
Dr Kristopher Paolino, MD has been appointed  
Principal Investigator on the trial.

## Data and CMC



Providing regulatory strategy and drafting  
Investigational New Drug Application for the  
use of ISLA-101 in PEACH study.

## Clinical Research Organisation



Database creation and management. Clinical  
trial support services. High quality CRO with  
significant expertise in the dengue human  
infection model (DHIM) that Island will be using  
in the PEACH study.

# KEY COLLABORATIONS & ALLIANCES

SUPPORTING FUTURE PIPELINE DEVELOPMENT



Research Collaboration Agreement to screen thousands of known molecules against host targets building upon the Fenretinide (ISLA-101) discovery sourced from these laboratories that the Company has licensed for use against Flaviviruses



Research and development collaboration with Griffith University to screen for active anti-viral molecules in a rational repurposing strategy. The small molecule libraries for Drug Discovery (GRIDD) Compounds Australia facility, using highly sensitive assays



Research collaboration agreement signed with Australia's largest drug library containing millions of molecules that can be searched for drug re-purposing and pipeline development



Cooperative Research and Development Agreement (CRADA) with the US Army in preparation for its Phase II clinical study for ISLA-101



Supply agreement with Catalent for manufacture of Fenretinide softgels for dengue fever trial participants



Right to reference National Cancer Institute IND for Isla-101



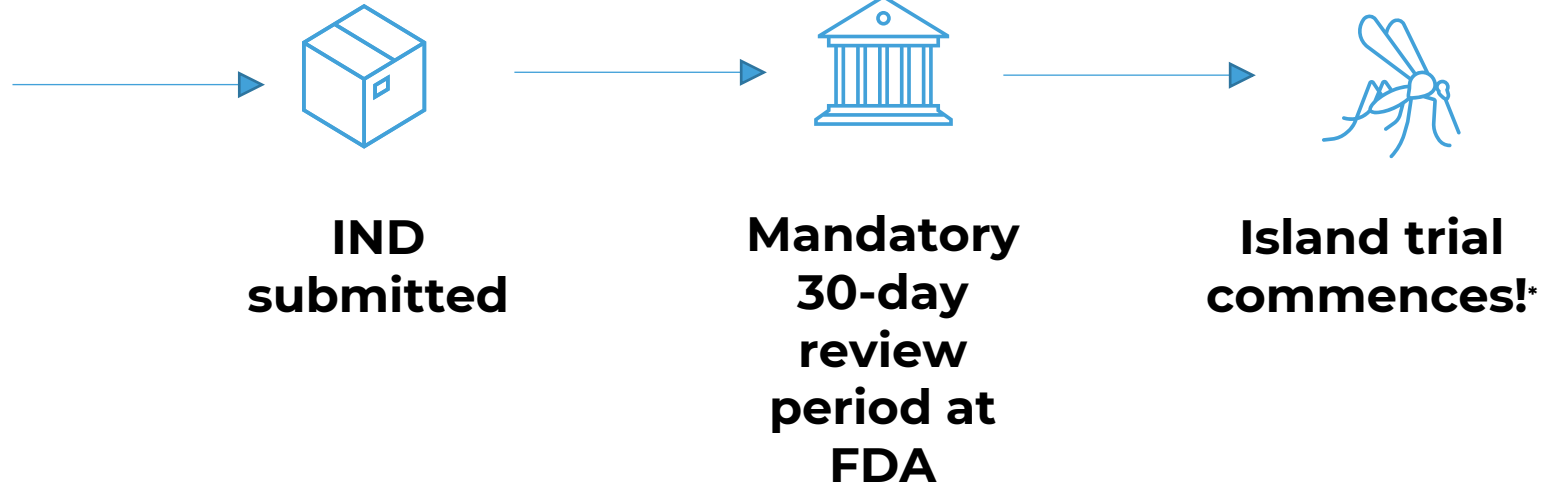
# PATHWAY / TIMING TO CLINICAL TRIALS

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**



# PHASE II DENGUE (PEACH) TRIAL STUDY IN DETAIL



Antiviral therapeutics

“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 18-45
- Willing to use contraception for the duration of the study
- Informed consent

### Exclusion

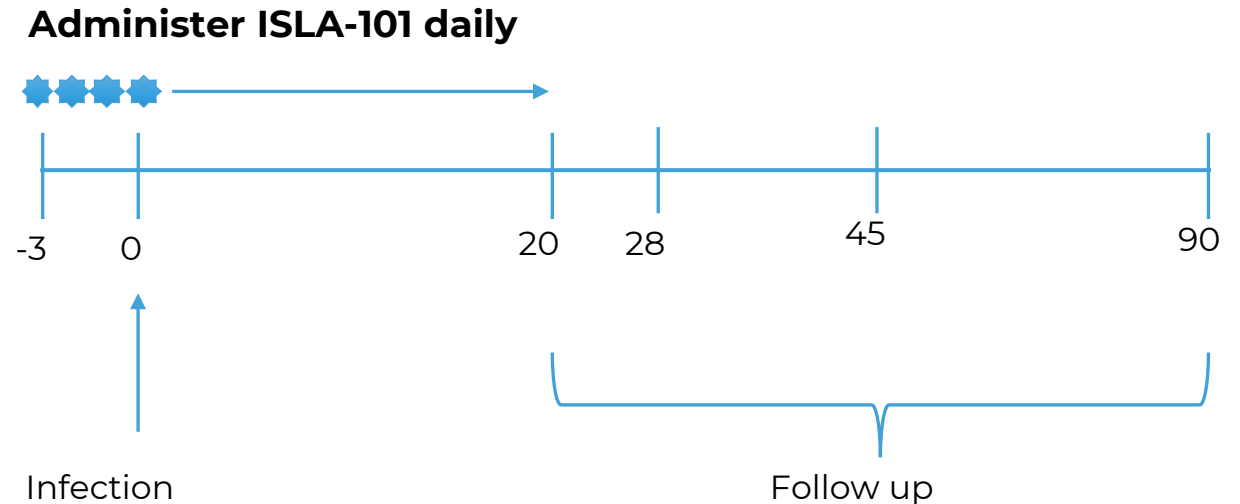
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

### 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

Island has recently engaged a third party virologist to investigate ~150 human relevant viruses, 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

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

## H2 FY 2022

- Drug substance manufactured
- Analytical method development
- Preliminary timeframe for clinical product manufacturing

## H1 FY 2023

- File IND
- Open IND
- Start screening subjects for PEACH\* trial
- First subject in PEACH trial
- Advance through PEACH cohorts

## H2 FY 2023

- Advance through PEACH cohorts
- Trial read out
- Meeting with FDA
- 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

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## MANAGEMENT TEAM & BOARD OF DIRECTORS



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



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



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



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

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**Prof. Stephen Thomas MD**



**Dr. Simon Tucker**



**ISLAND**

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**Island Pharmaceuticals**

**Limited**

**ACN 641 183 842**