



# SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA)  
2022 Annual General Meeting  
CEO's presentation  
November 2022

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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.



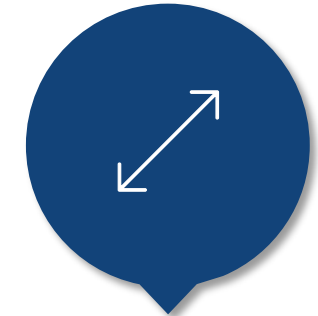
## Positive results in aggressive models

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 CHALLENGE



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

World Health Organisation, 13 October 2022



**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 arbovirolosis 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.



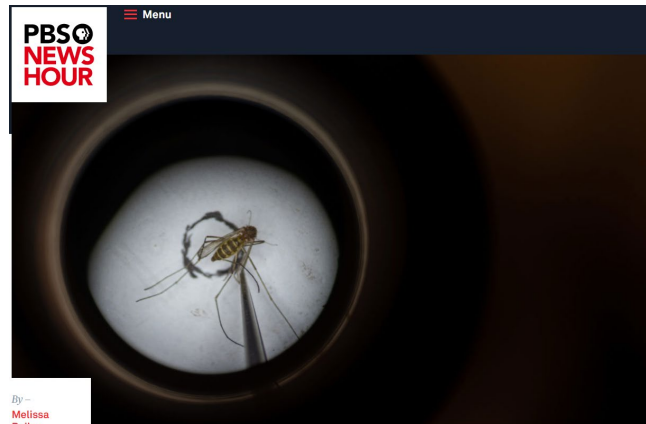
Singapore is facing a dengue fever 'emergency' and peak season has only just begun

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

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



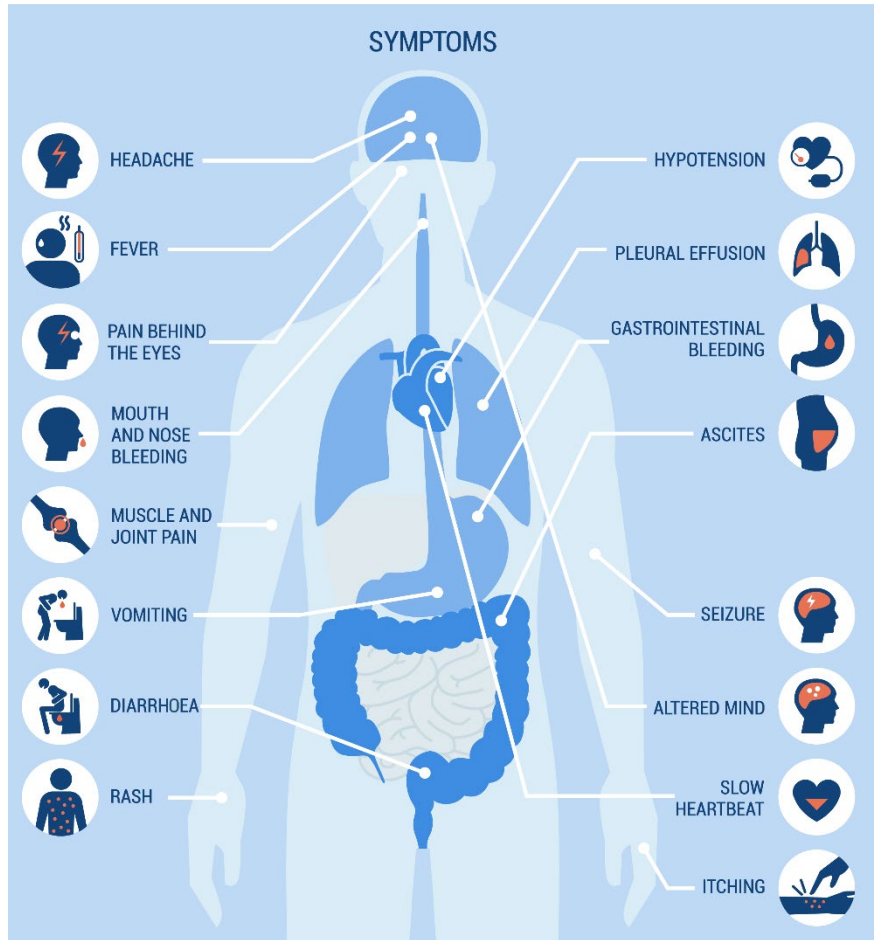
In temperate Nepal, climate change paves way for tropical dengue fever

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

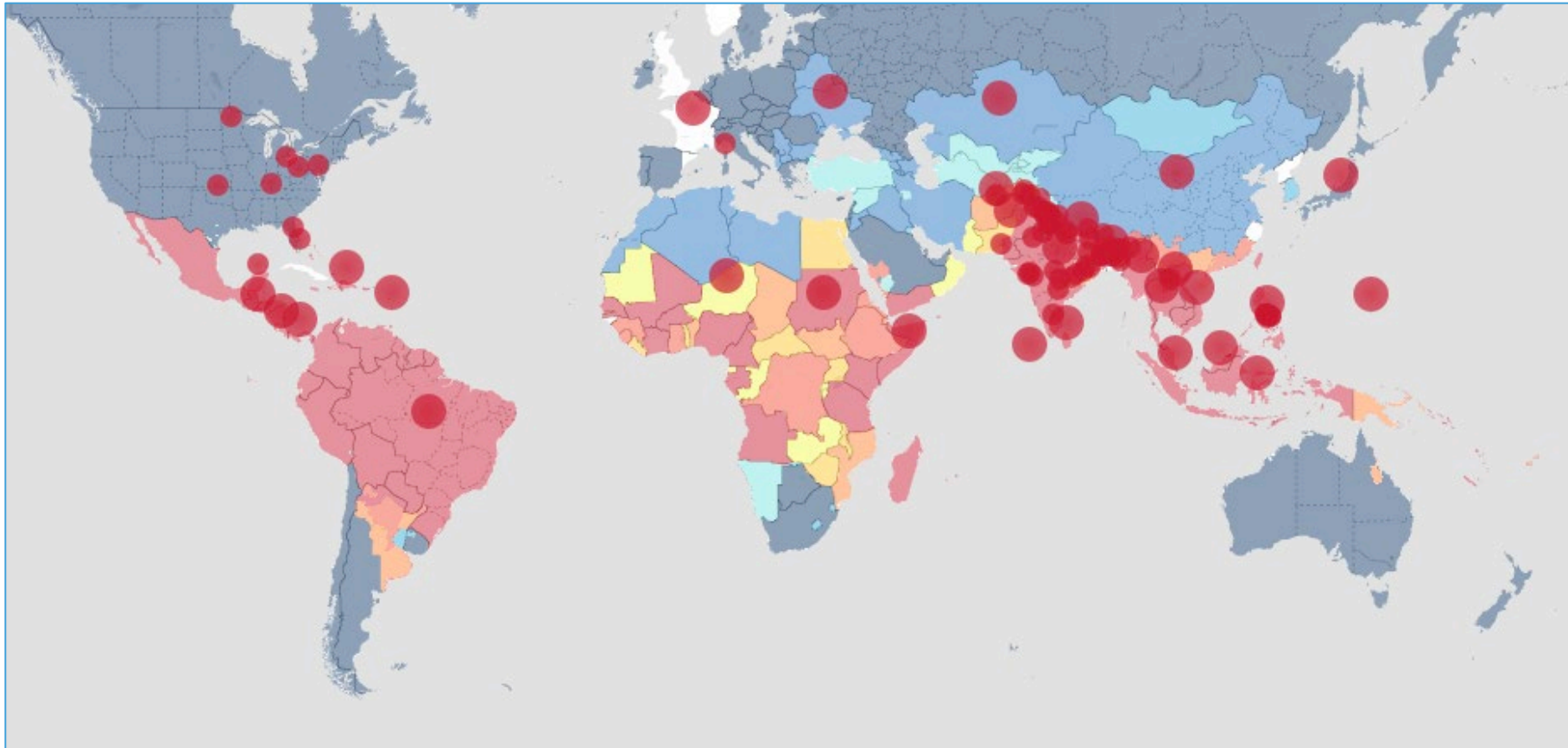
Strong animal and human model results

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.

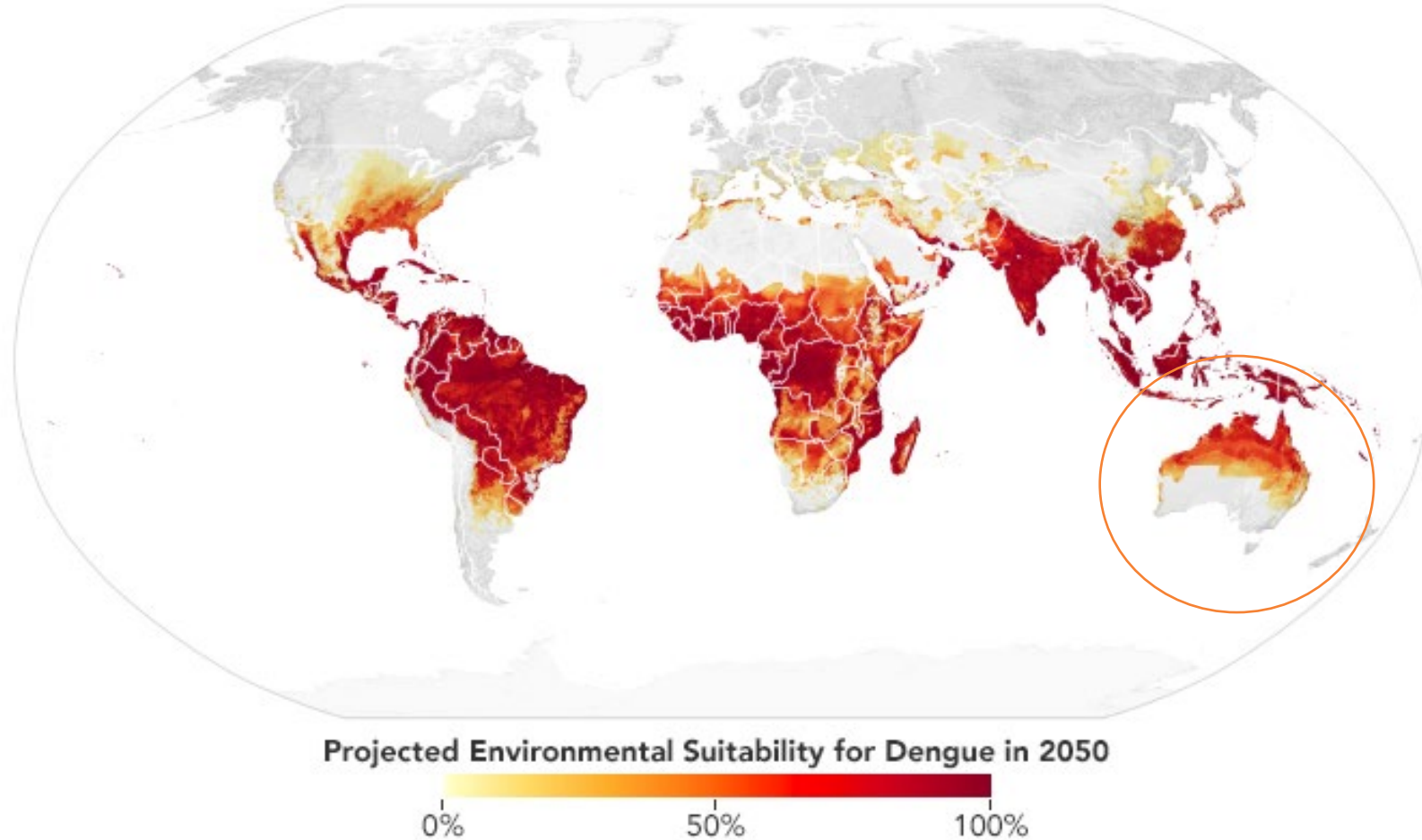
Source.

● 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

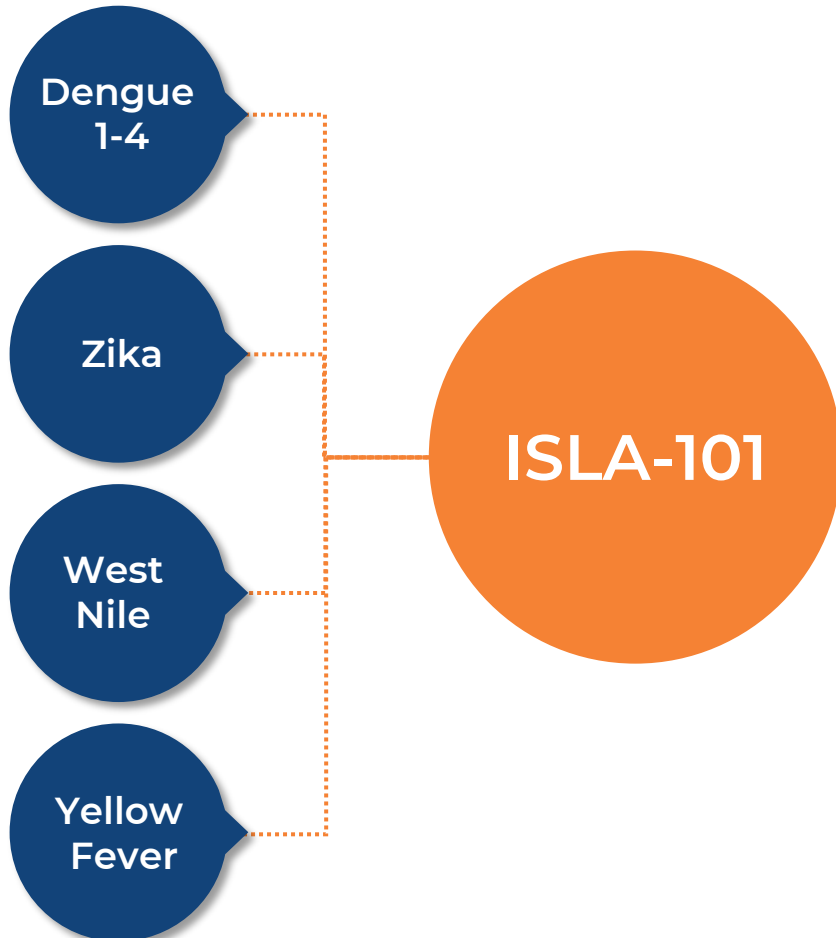
Multiple regulatory jurisdictions have reviewed ISLA-101 as having a well established safety profile

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

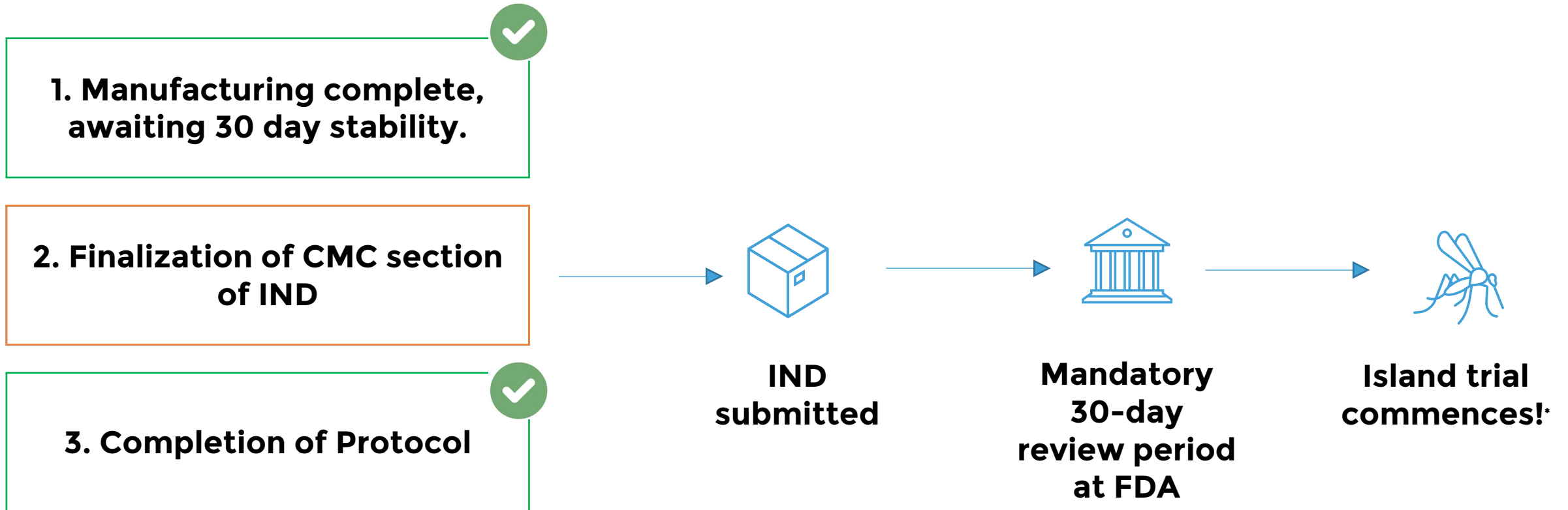
DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES (A SUBGROUP OF ARBOVIRUSES) IN MULTIPLE MODELS OF INFECTION



- 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



# 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 18-55
- Willing to use contraception for the duration of the study
- Informed consent

### Exclusion

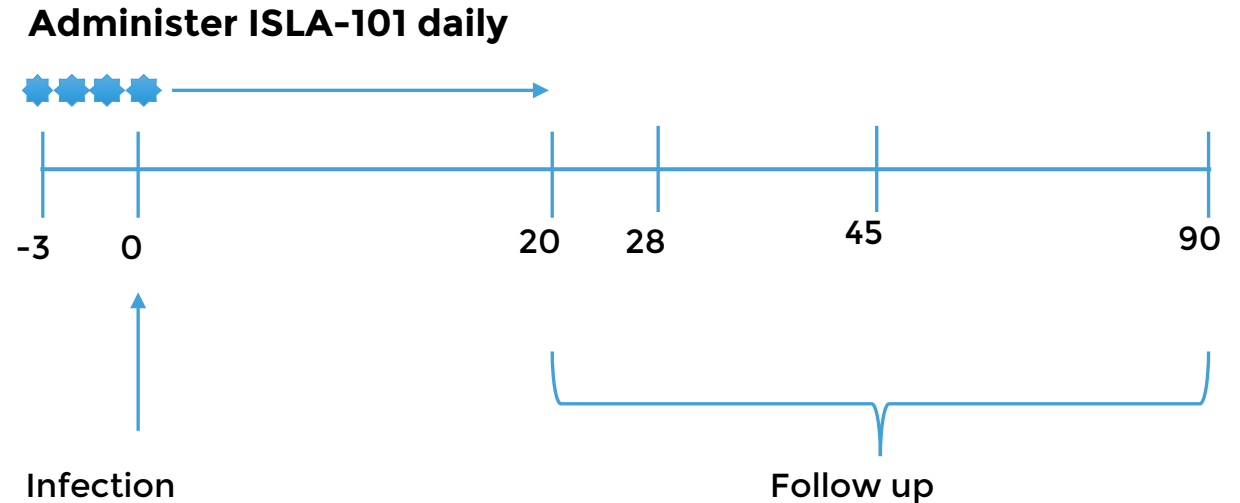
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

### 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



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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

# TIMELINE NOW FALLING INTO PLACE

**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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