

29 November 2022

ASX Announcement Island to present at World Antiviral Congress 2022

MELBOURNE Australia, 29 November 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to release a copy of the presentation that will be delivered at the World Antiviral Congress 2022 in San Diego, USA on 28 November – 1 December 2022.

The World Antiviral Congress is an invitation only event, focused on helping companies to accelerate their antiviral research. This year's theme is *"Bringing translational antiviral drug discovery and development to the market"*.

"The Congress presents a valuable platform for Island to present to the world's leading experts in the field of infectious disease about the vast potential around our investigational dengue fever drug, ISLA-101" said Dr David Foster.

"We will also discuss opportunities we have to rapidly progress new treatments for emerging viral threats, and we welcome discussions with prospective commercial partners and collaborators," said Dr David Foster.

Island presentation details

Date & time: Tuesday 29 November at 4.50pm PDT
Presenter: Dr David Foster, CEO, Island Pharmaceuticals
Presentation title: A repurposing antiviral solution for the prevention and treatment of Dengue

A copy of Island's presentation is attached.

Approved for release to the ASX by:

Dr Paul MacLeman
Executive Chairman
Island Pharmaceuticals Ltd
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

About Island Pharmaceuticals

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



dengue² 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 for more on Island.



ISLAND

PHARMACEUTICALS

Antiviral therapeutics

SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA)
World Antiviral Congress

November 2022

DISCLAIMER

This presentation has been prepared by Island Pharmaceuticals Limited (ABN 641 183 842) (Company or Island Pharmaceuticals).

Not an offer or financial product advice

The Company is not licensed to provide financial product advice. This presentation is not and should not be considered, and does not contain or purport to contain, an offer or an invitation to sell, or a solicitation of an offer to buy, directly or indirectly any securities, to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful nor shall it (or any part of it), or the fact of its distribution, form the basis of, or be relied on in connection with or act as any inducement or recommendation to enter into, any contract whatsoever relating to any securities. This presentation is for information purposes only and is not a prospectus, product disclosure statement, pathfinder document for the purposes of section 734(9) of the Australian Corporations Act 2001 (Cth) (Corporations Act) or other offer document under Australian law or the law of any other jurisdiction. This presentation does not constitute an invitation to apply for or purchase Securities and does not include any application form for Securities. This presentation does not constitute an advertisement for an offer or proposed offer of Securities. Neither this presentation nor anything contained in it shall form the basis of any contract or commitment and it is not intended to induce or solicit any person to engage in, or refrain from engaging in, any transaction. Nothing in this presentation constitutes legal, financial, tax or other advice. Recipients of the presentation should conduct their own investigation, evaluation and analysis of the business and other data and information set out in the presentation.

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.

Future performance

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.


Forward-looking statements, including projections, guidance on future operations, earnings and estimates (if any), are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. No representation is given that the assumptions upon which forward looking statements may be based are reasonable. This presentation contains statements that are subject to risk factors associated with the Group's industry. These forward-looking statements may be affected by a range of variables which

could cause actual results or trends to differ materially, including but not limited to earnings, capital expenditure, cash flow and capital structure risks and general business risks.

No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company). In particular, but without limitation, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward looking statements in this presentation will actually occur. Actual operations, results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Any forward looking statements in this presentation speak only as of the date of this presentation.

Subject to any continuing obligations under applicable law, the Company disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this presentation to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based.

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



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.



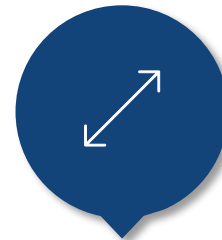
Positive results in aggressive models

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



Priority Review Voucher potential

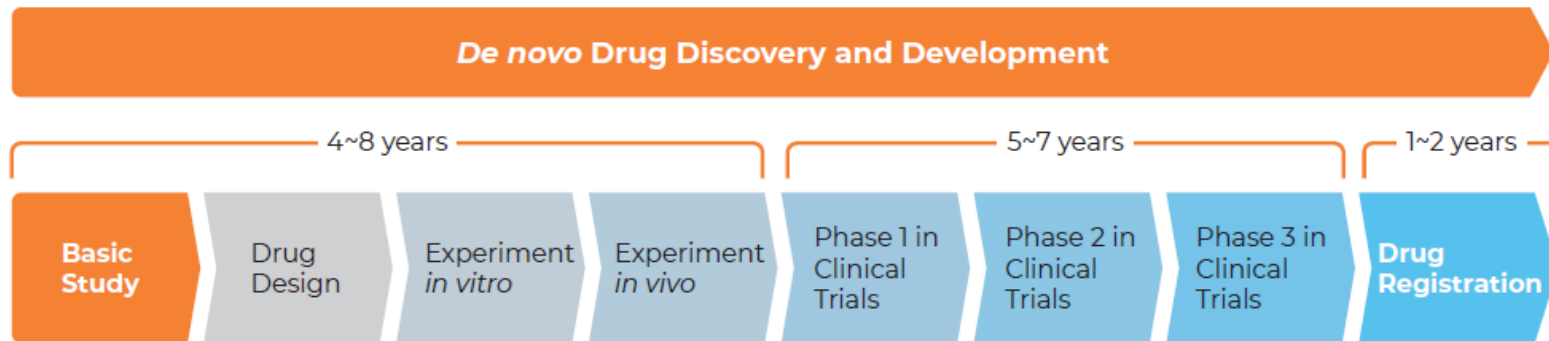
For ISLA-101 at the time of FDA approval.
Last ten PRVs sold for an average of
US~\$110M.



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



 **ISLAND**
PHARMACEUTICALS
Antiviral therapeutics

**“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

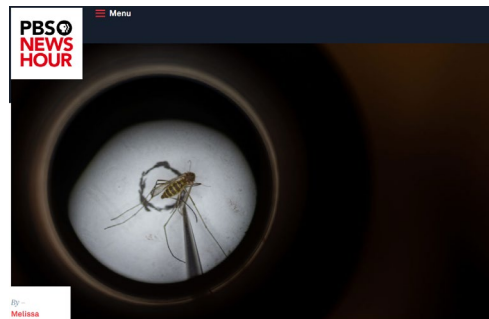


The researchers found 2.4 times the rate of arbovirosis as originally reported, including coinfections, suggesting underestimation of the incidence of the three viruses. However, future research is needed to provide up-to-date incidence estimates of each virus.



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



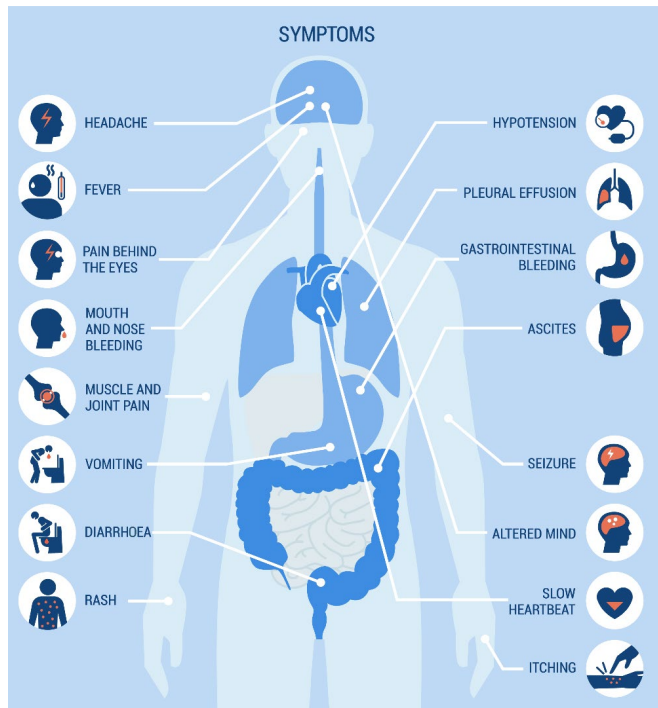
In temperate Nepal, climate change paves way for tropical dengue fever

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

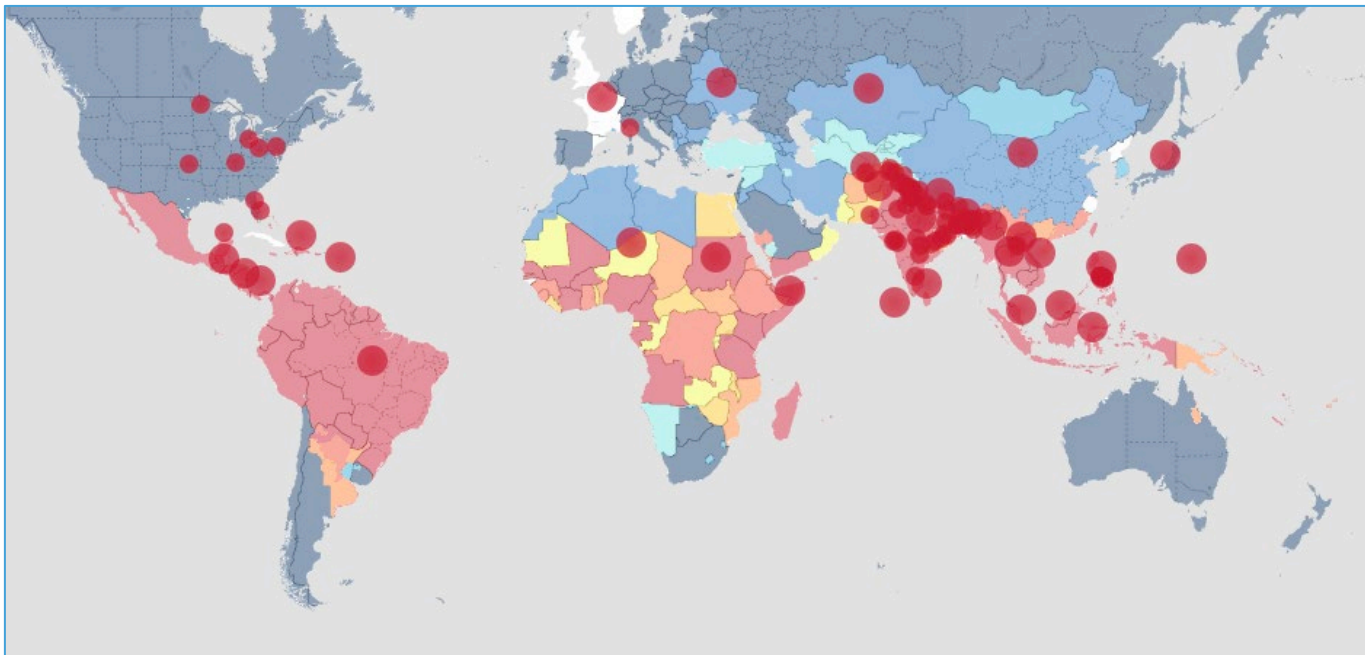
ISLA-101 has both therapeutic and prophylactic potential

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.

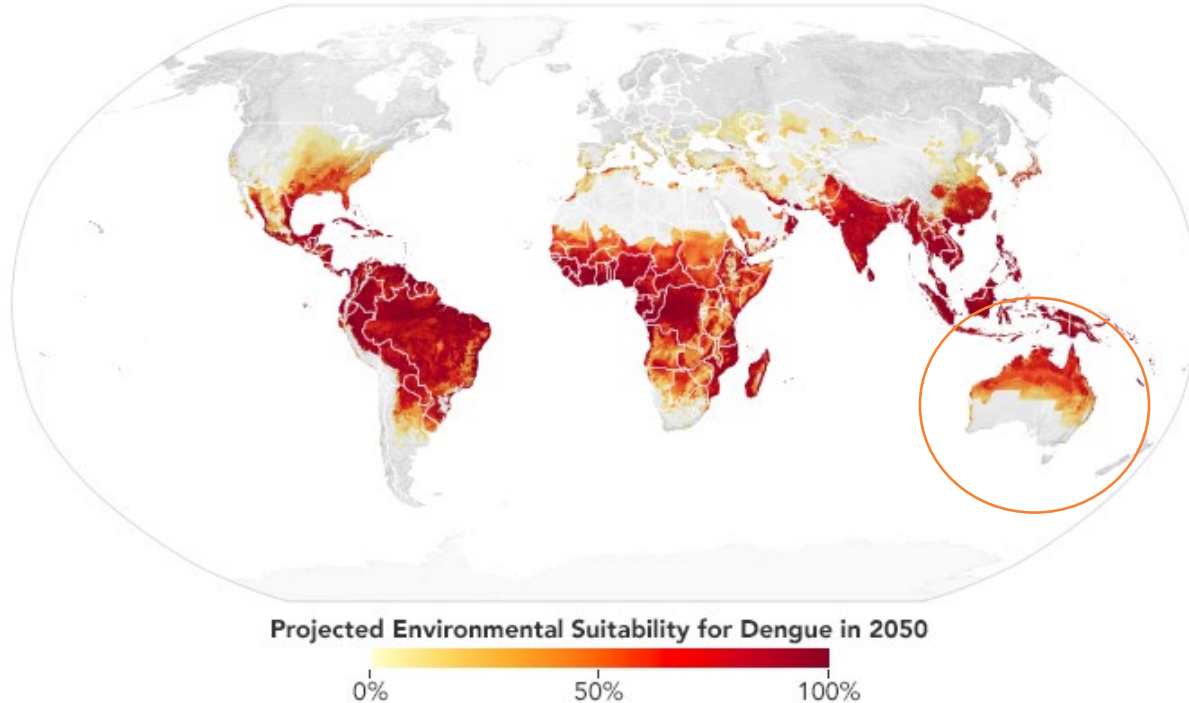
Source:

● 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.)



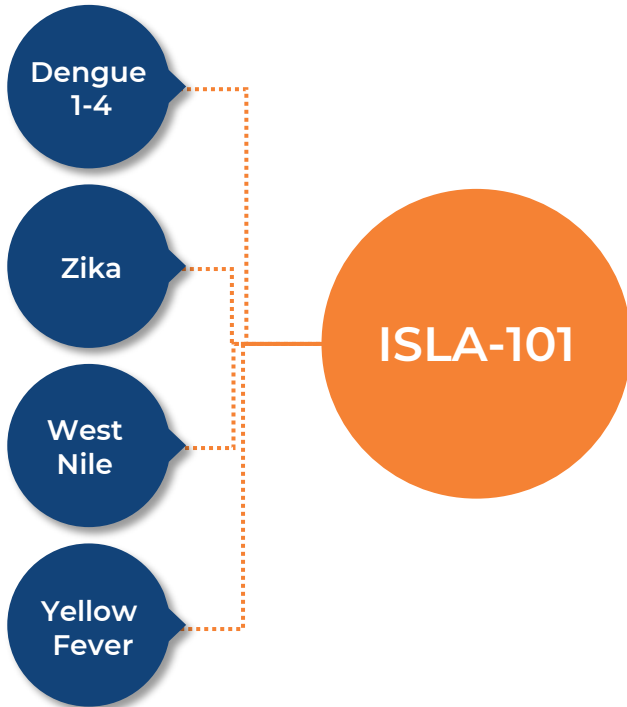
ISLA-101



ISLAND
PHARMACEUTICALS
Antiviral therapeutics

ISLA-101 BROAD ACTIVITY EVIDENT

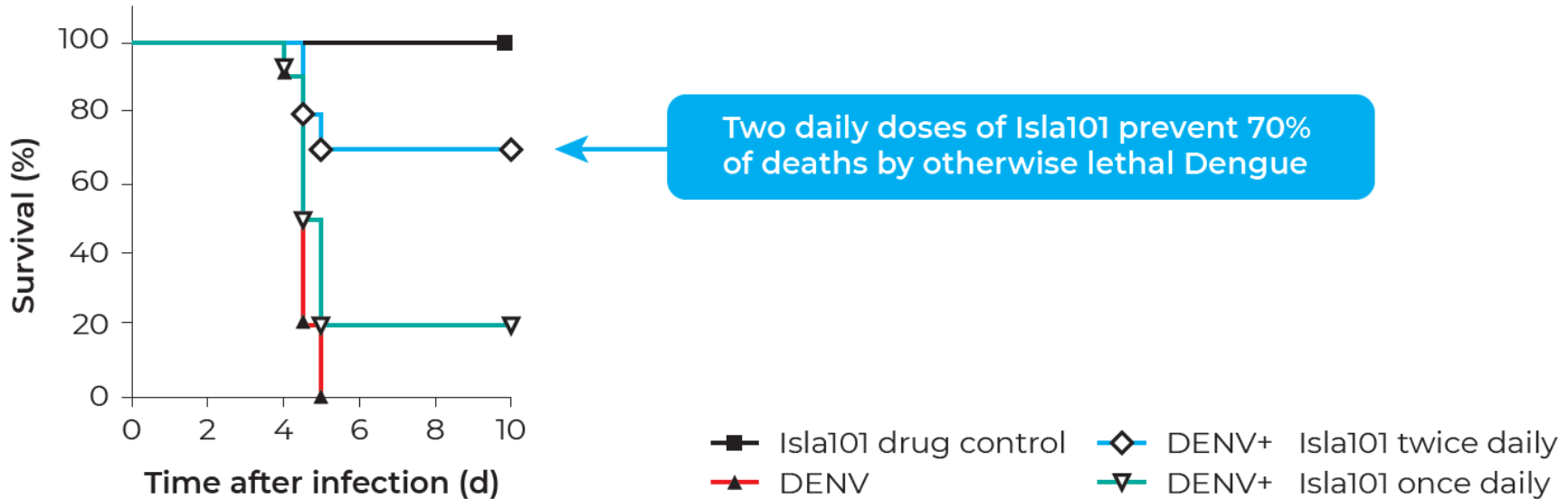
DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES (A SUBGROUP OF ARBOVIRUSES) IN MULTIPLE MODELS OF INFECTION



- 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

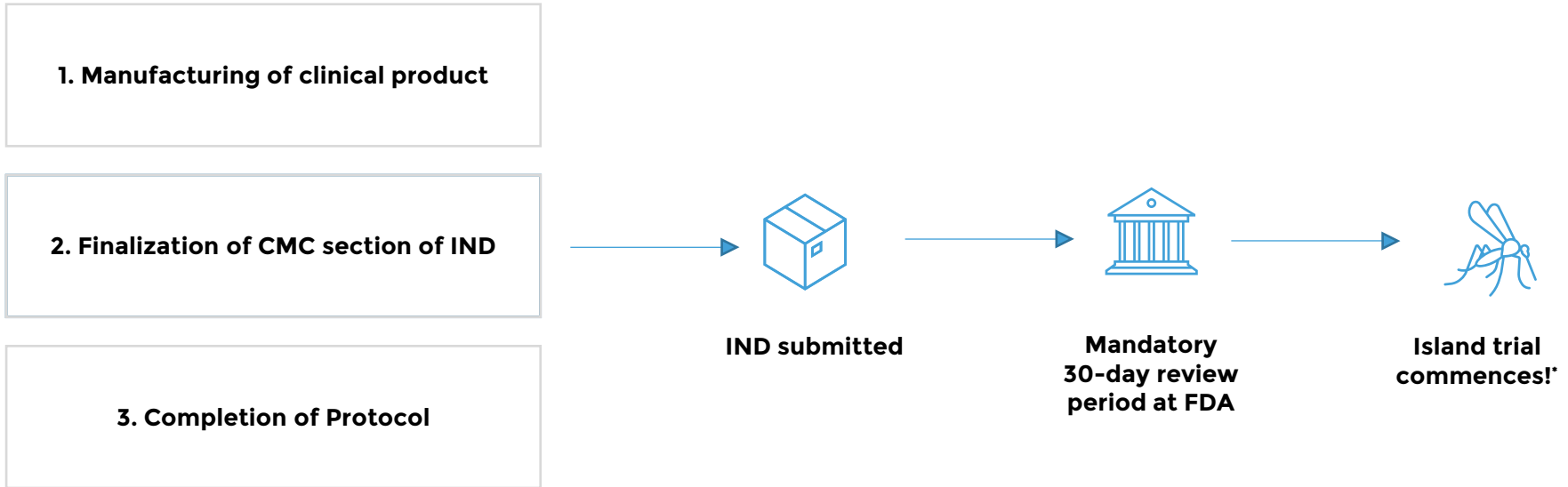
ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.



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

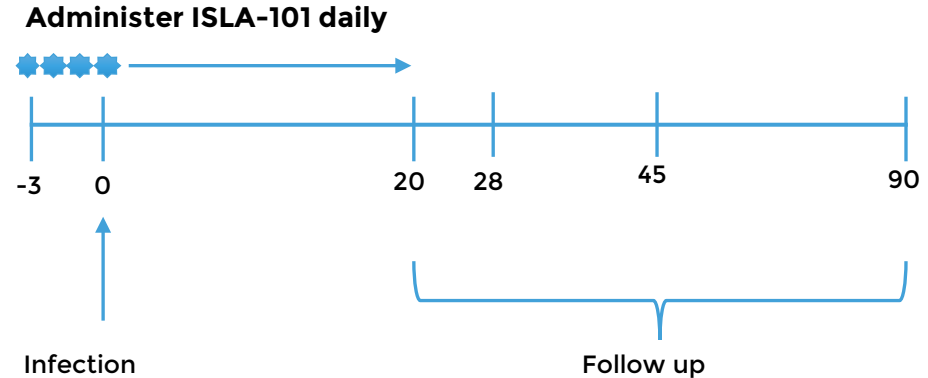
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

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



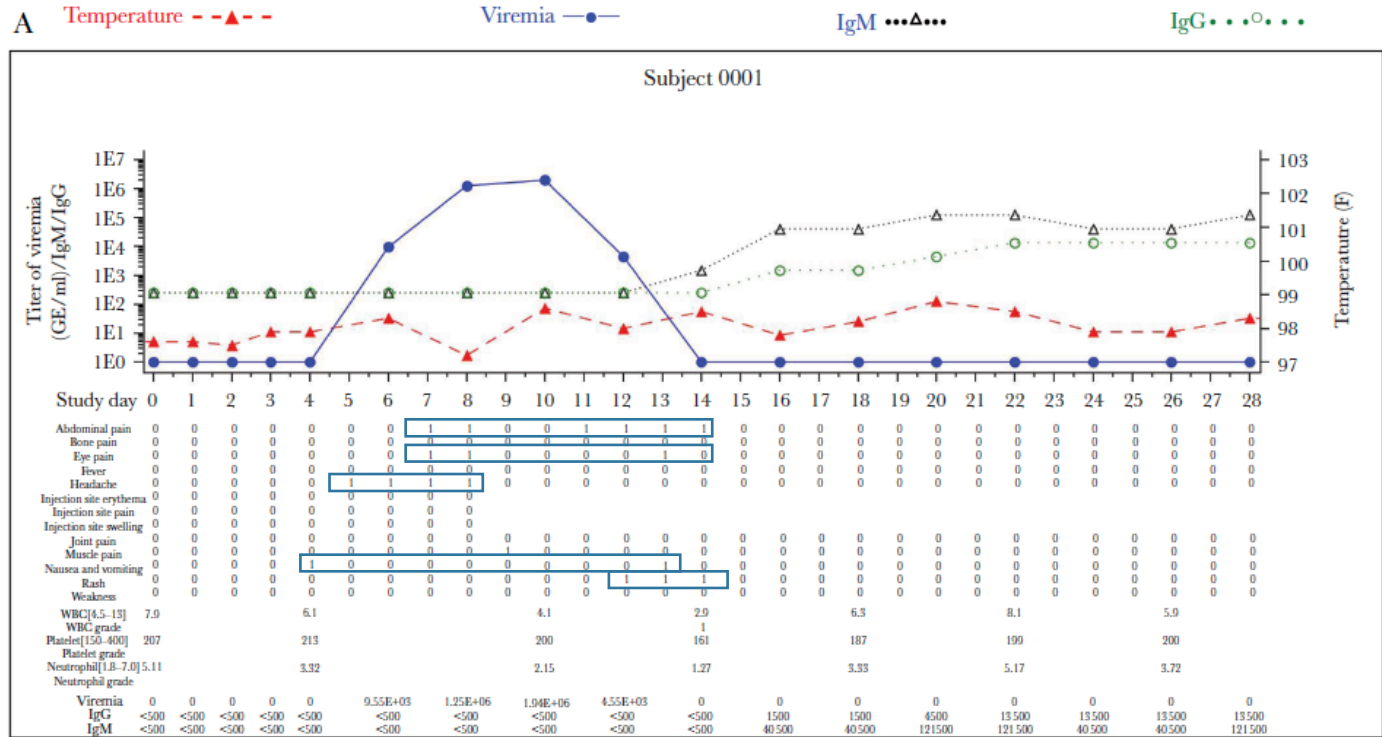
The study will be run at SUNY Upstate Medical University Syracuse, New York

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

 **ISLAND**
PHARMACEUTICALS
Antiviral therapeutics

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.



David Foster
Chief Executive Officer & Executive Director
dfoster@islandpharmaceuticals.com

Authorized for release by Paul MacLeman, Executive Chairman

www.islandpharmaceuticals.com
Registered office: Suite 201, 697 Burke Rd, Camberwell VIC 3124, Australia

Island Pharmaceuticals Limited

ACN 641 183 842