



15 June 2022

ASX Announcement

Island to present at BIO International Convention

MELBOURNE Australia, 15 June 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA) is pleased to advise that Island's CEO, Dr David Foster has been selected to present at the BIO International Convention in San Diego, California on Wednesday 15 June, US time.

BIO is the world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries. The BIO International Convention is the world's largest gathering of the biotechnology industry. It attracts more than 15,000 biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships.

New presentation material

Attached is a copy of the presentation that Dr Foster will present at the conference. New material includes Phase 1 data from SUNY Upstate and Walter Reed which will form the basis of Island's Phase 2 PEACH¹ study control data and an update to the upcoming milestones slide. (Refer to ASX announcement dated 15 June 2022 for more information.)

Presentation details

Date and time: Wednesday, 15 June, 2022 at 11:45am PDT
Conference: BIO International Convention 2022
Room: Live in Company Presentation Theater 4

One-on-one meetings are also being scheduled via the BIO partnering system or by contacting Island directly (details below).

Approved for release to the ASX by:

Dr Paul MacLeman
Executive Chairman
Island
Pharmaceuticals Ltd
info@islandpharmaceuticals.com

¹ A Phase 2a, Randomized, Double blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model



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 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 for more on Island.



ISLAND

PHARMACEUTICALS

Antiviral therapeutics

**SOLVING URGENT
VIRAL DISEASE
THREATS**

(ASX: ILA)

BIO June 2022

DISCLAIMER

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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

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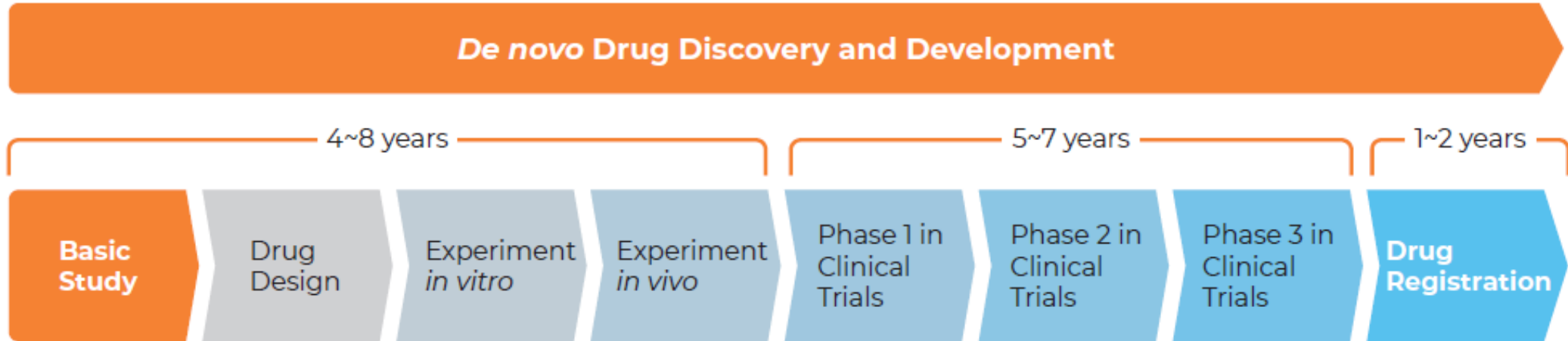
Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.

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

- Advancing lead drug ISLA-101 toward Phase 2 “PEACH”^{*} clinical trial for the prevention 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
- Positive results in aggressive animal and human cellular models of dengue fever and Zika infections as well as data in a range of other flaviviruses
- 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



Reduced time, cost and risk

THE CHALLENGE



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

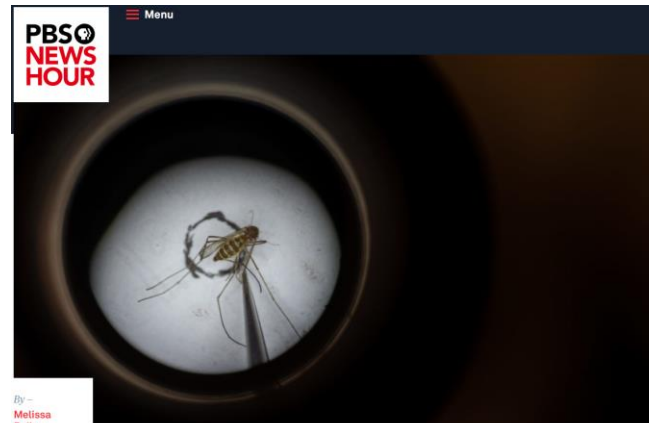


The researchers found 2.4 times the rate of arbovirolosis as originally reported, including coinfections, suggesting underestimation of the incidence of the three viruses. However, future research is needed to provide up-to-date incidence estimates of each virus.



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

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



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



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



BRYTFMONLINE



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

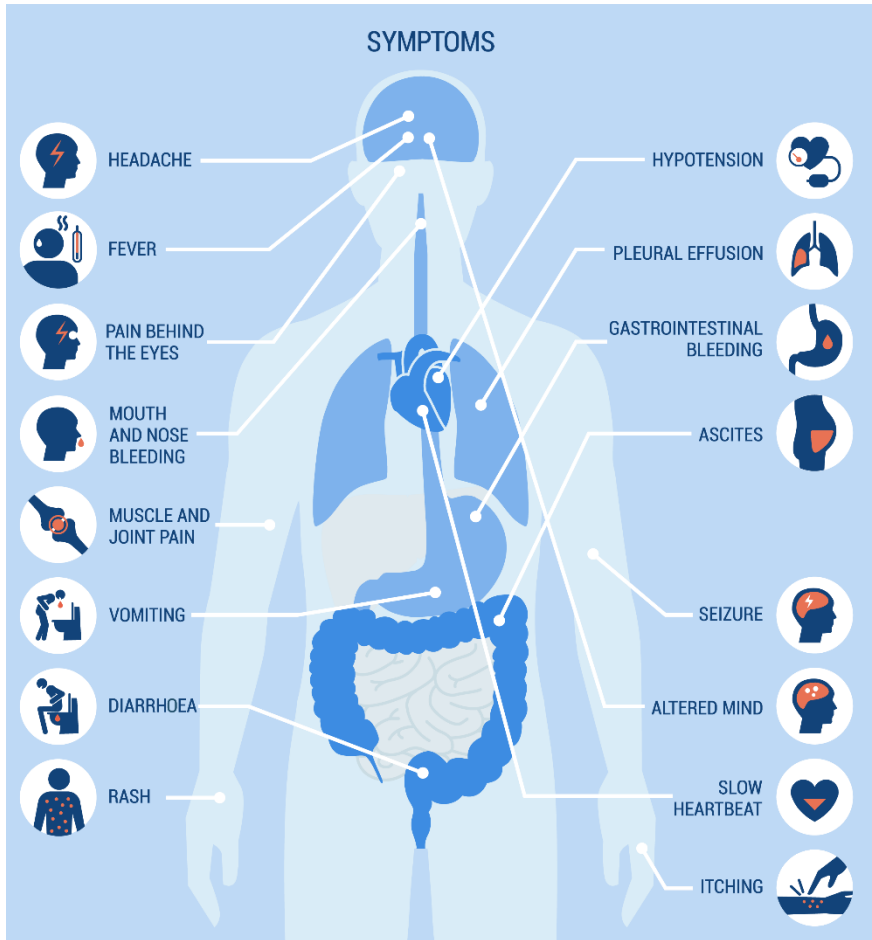
Colombia issues dengue fever alert

by NEWS DESK

November 14, 2021

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

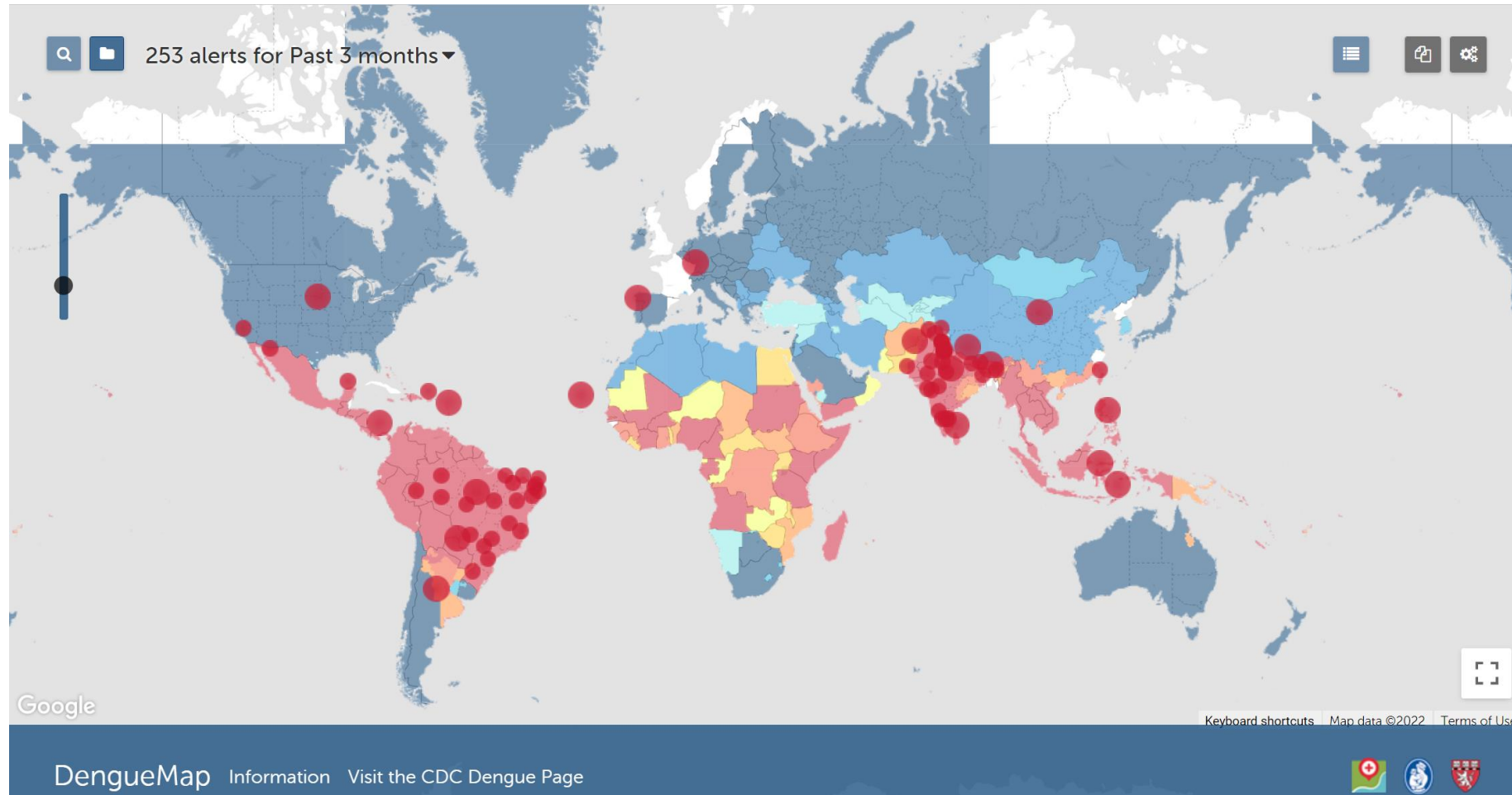
ISLA-101 has both therapeutic and prophylactic potential

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.

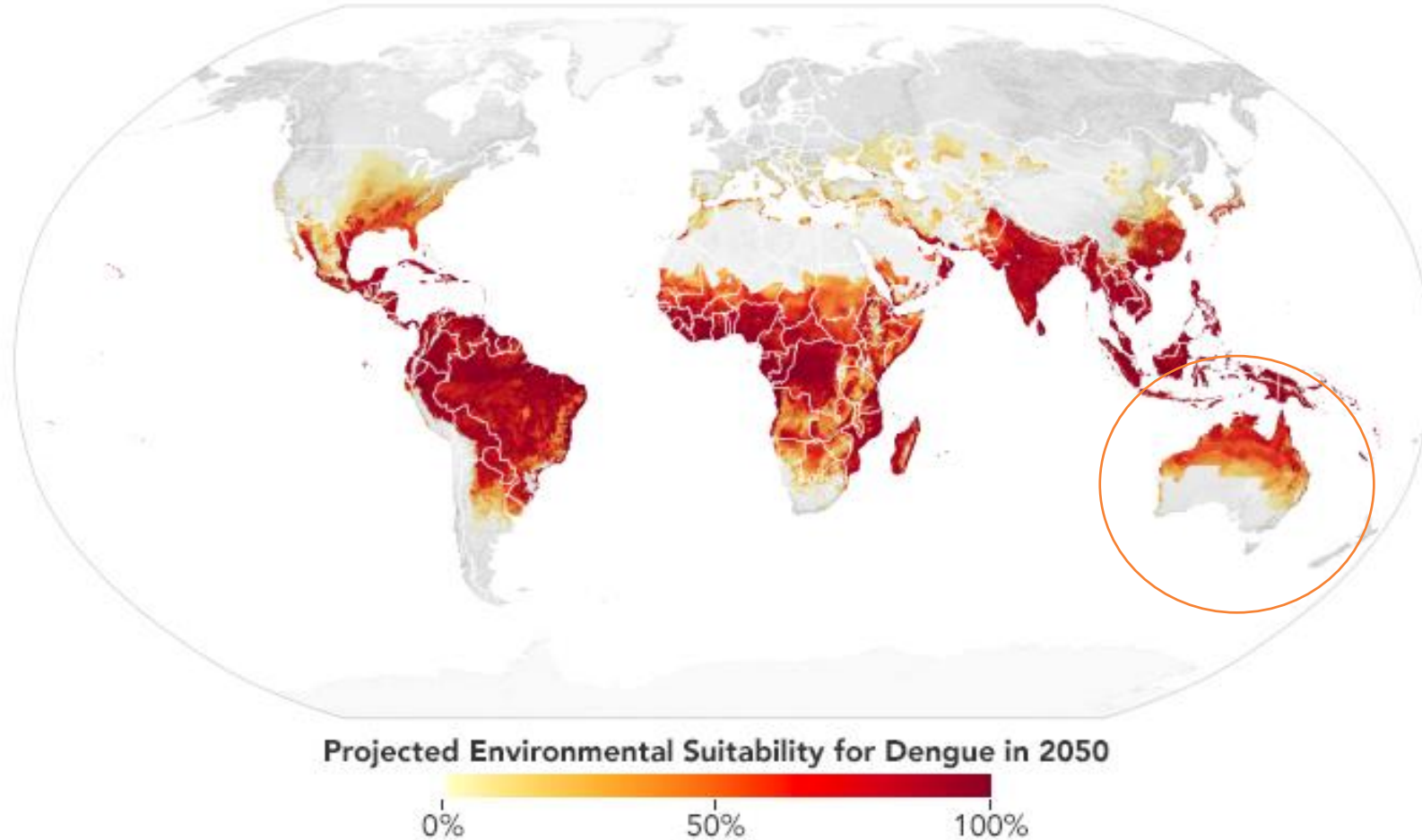
Source.

● 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



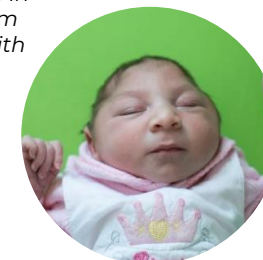
Vaccine

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



ISLAND
PHARMACEUTICALS
Antiviral therapeutics

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

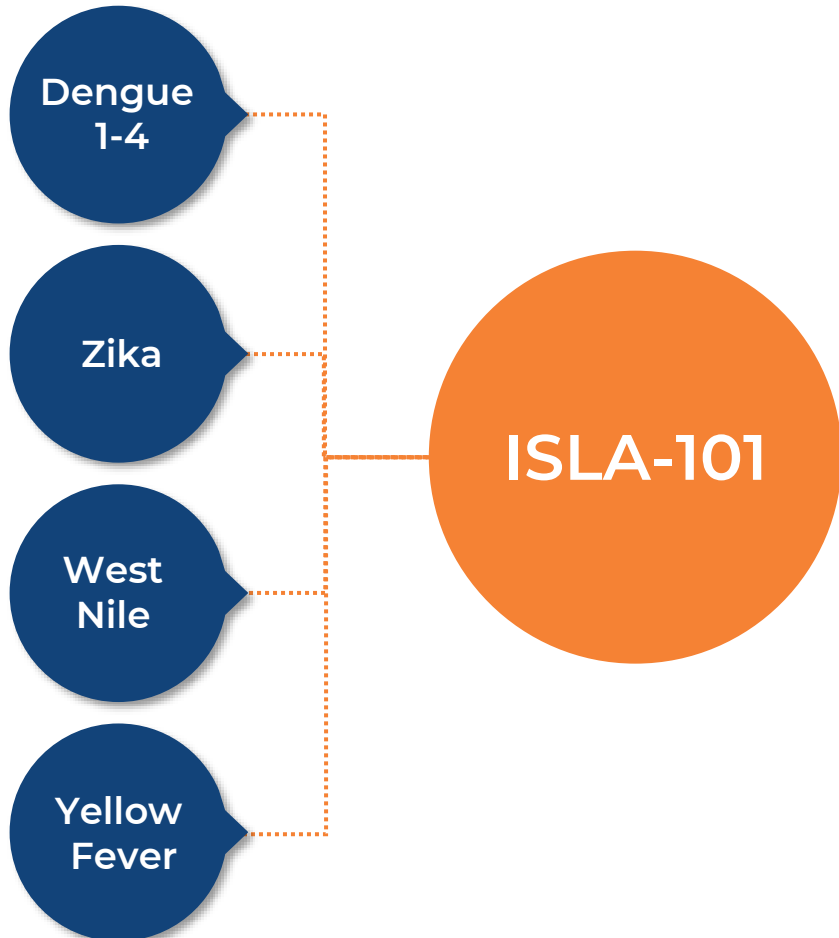


Capitalising on millions spent

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

ISLA-101 BROAD ACTIVITY EVIDENT

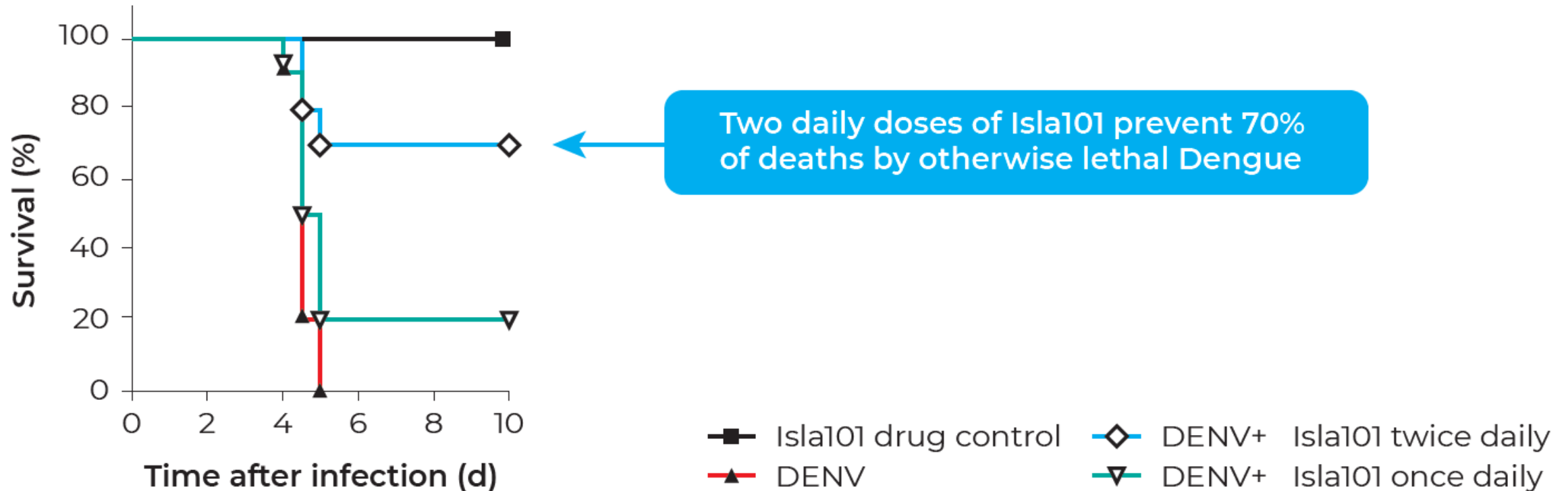
DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES (A SUBGROUP OF ARBOVIRUSES) IN MULTIPLE MODELS OF INFECTION



- 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

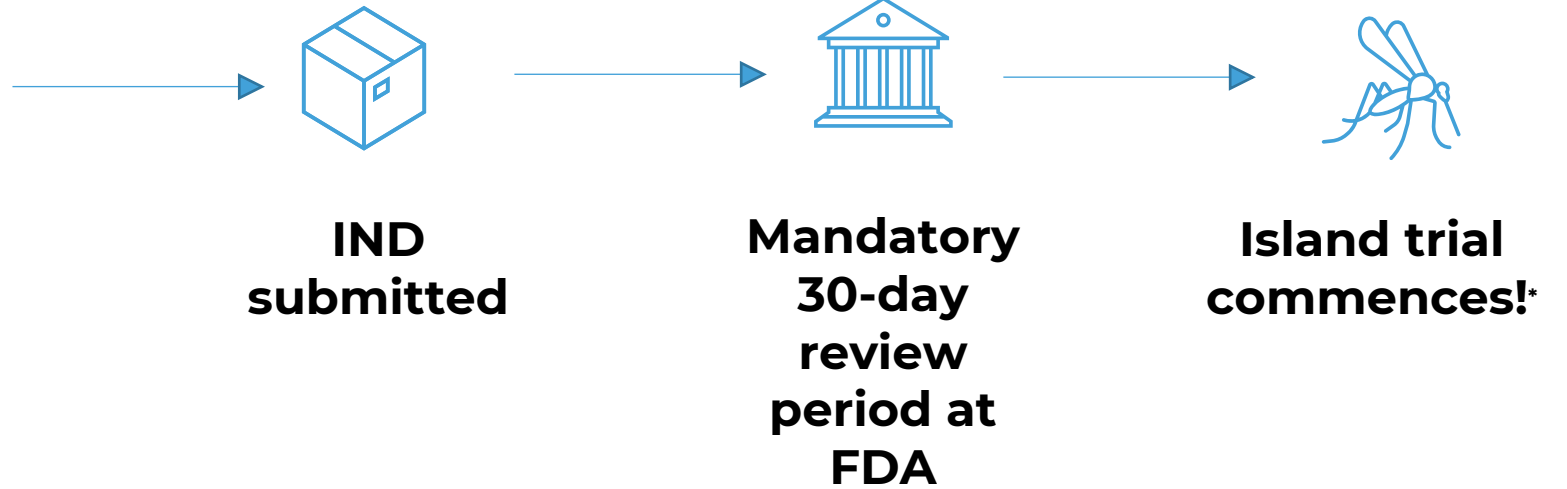
PATHWAY / TIMING TO CLINICAL TRIALS

MULTIPLE WORKSTREAMS WILL TAKE US TO FDA REVIEW OF OUR IND

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

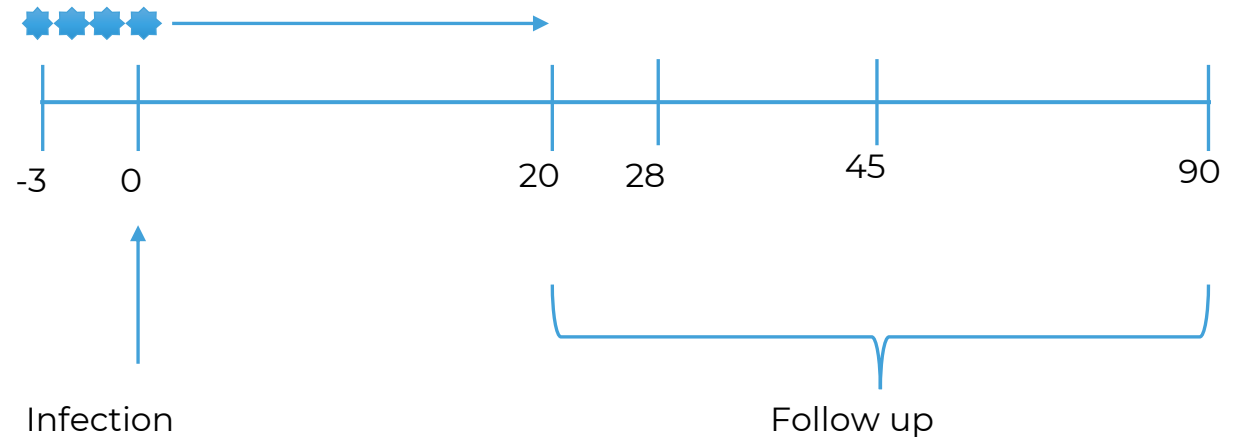
Primary endpoint

- 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

Administer ISLA-101 daily



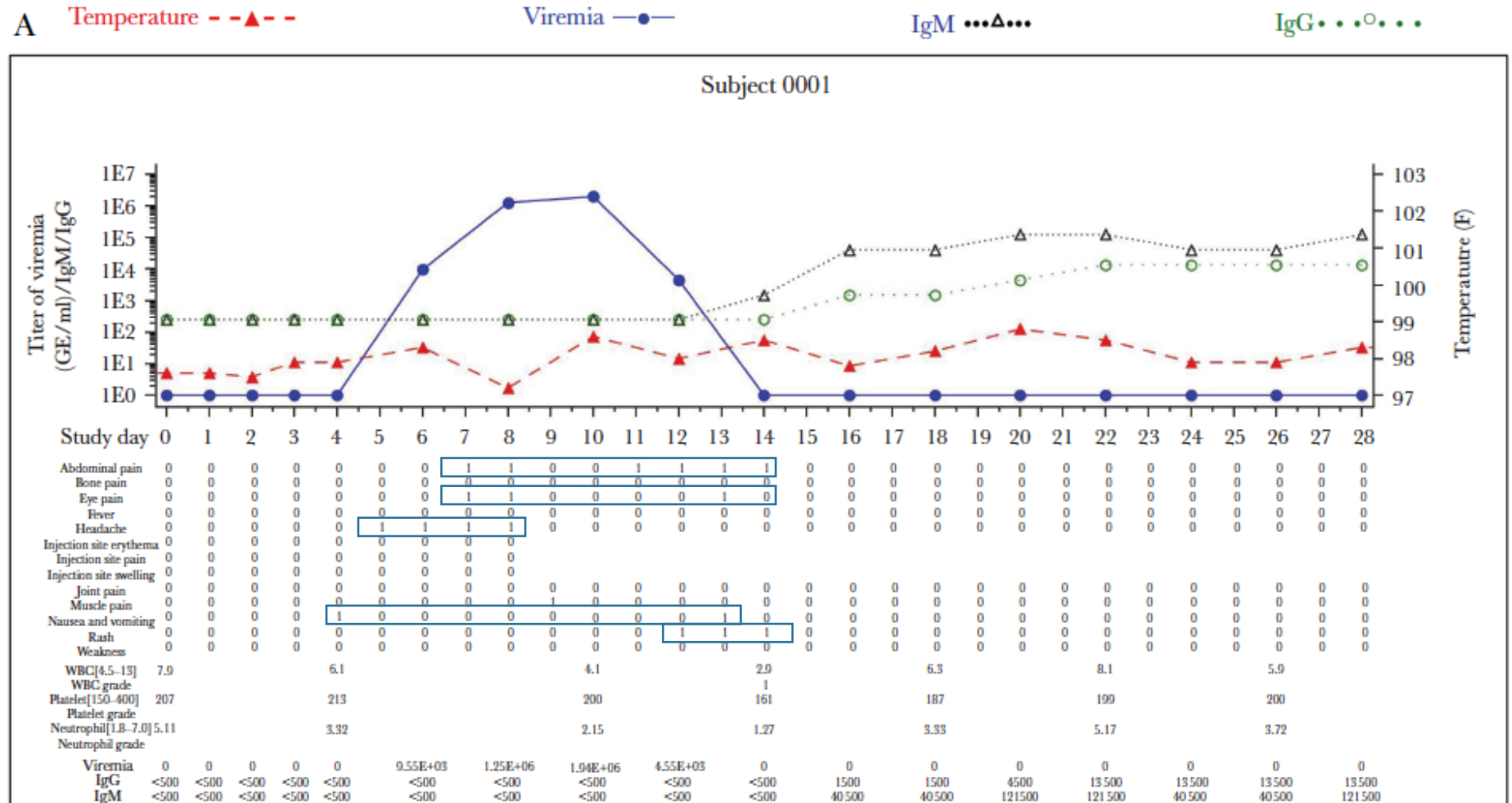
The study will be run at SUNY Upstate Medical University Syracuse, New York

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



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

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

H1 FY 2023

- Clinical material manufactured
- File IND
- Open IND
- Start screening subjects for PEACH* trial
- First subject in PEACH trial

H2 FY 2023

- 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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ISLAND

PHARMACEUTICALS

Antiviral therapeutics

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
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ACN 641 183 842