



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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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)

PAC Partners Inaugural Healthcare
conference – April 2022

DISCLAIMER

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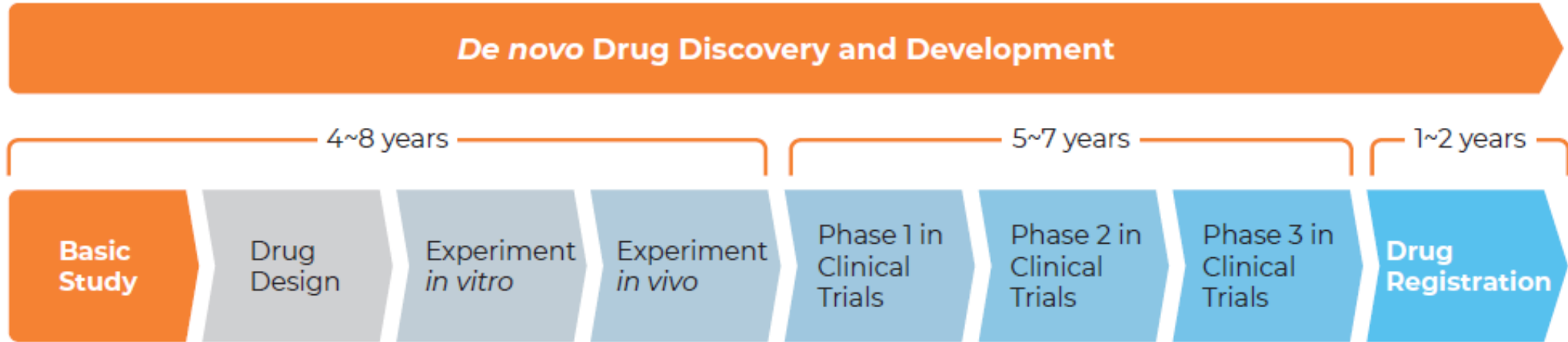
Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.

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



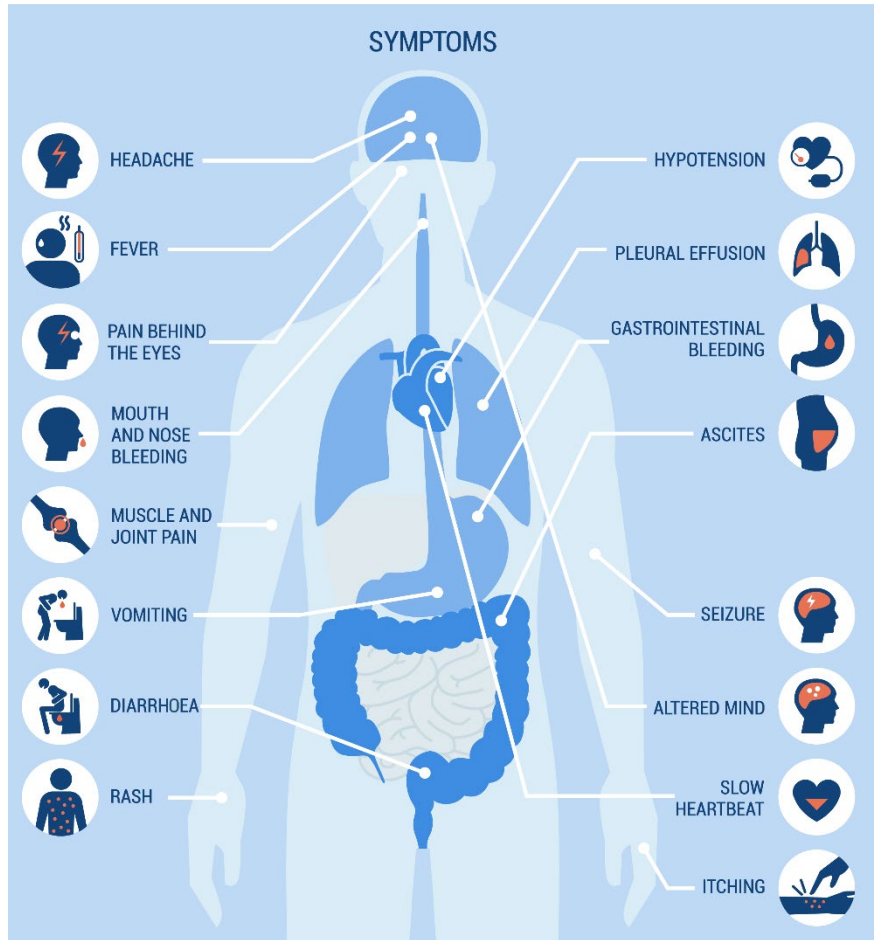
By Chris Barrett

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

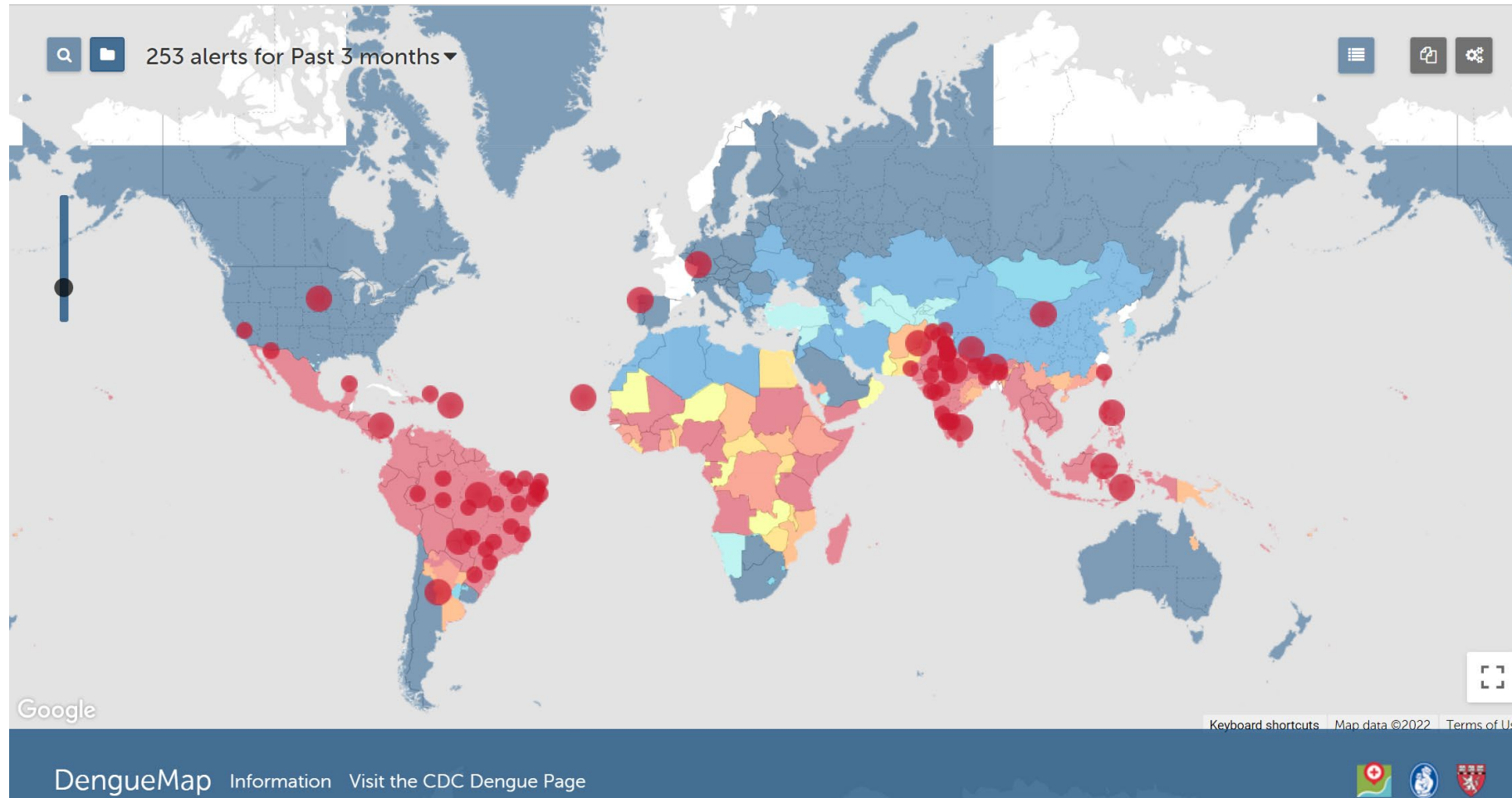
ISLA-101 has both therapeutic and prophylactic potential

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.

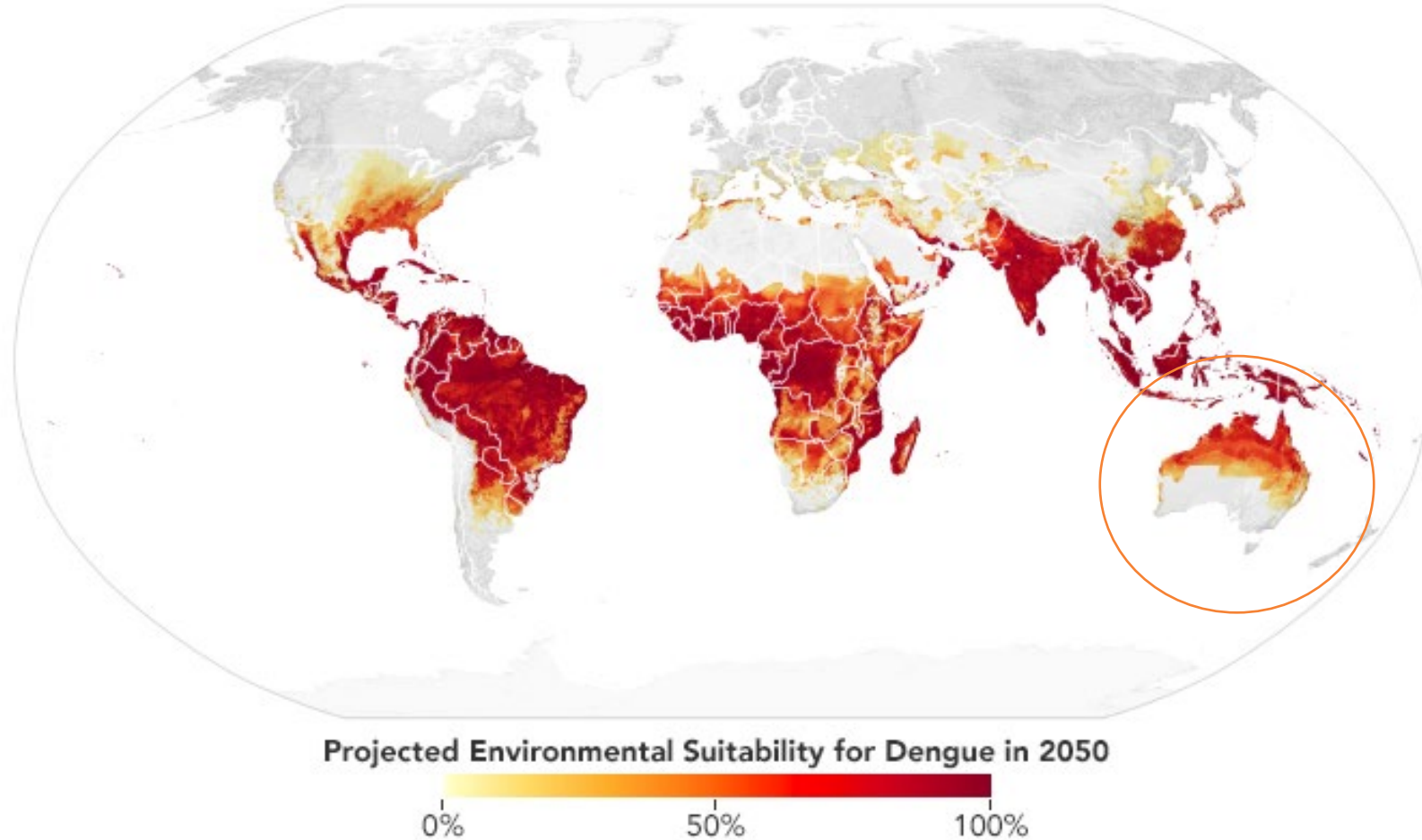
Source.

● 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



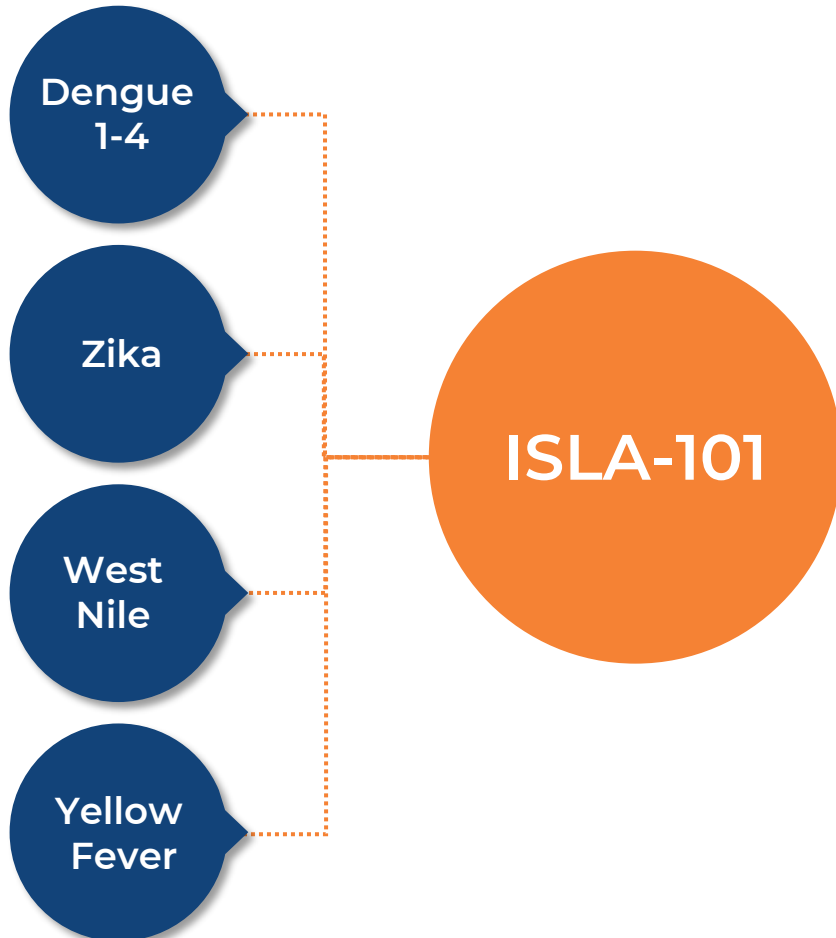
ISLA-101



ISLAND
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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)

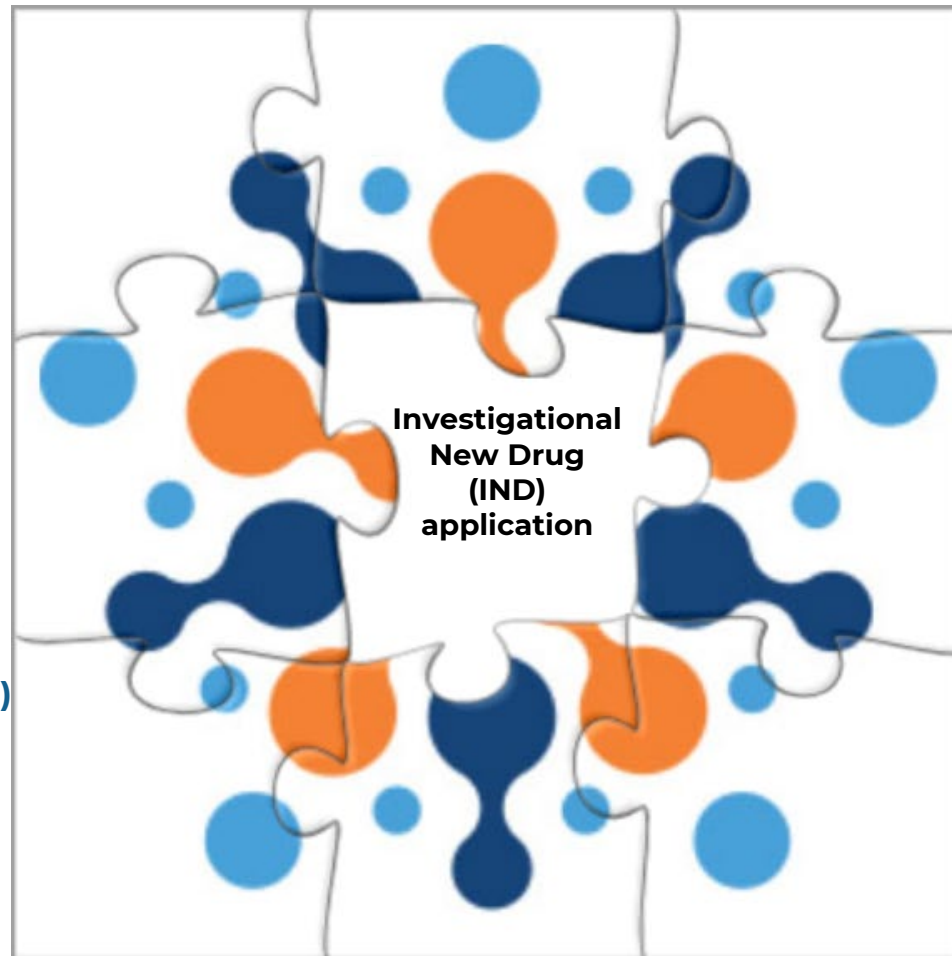
Summary of existing human data (complete)

- ✓ ~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

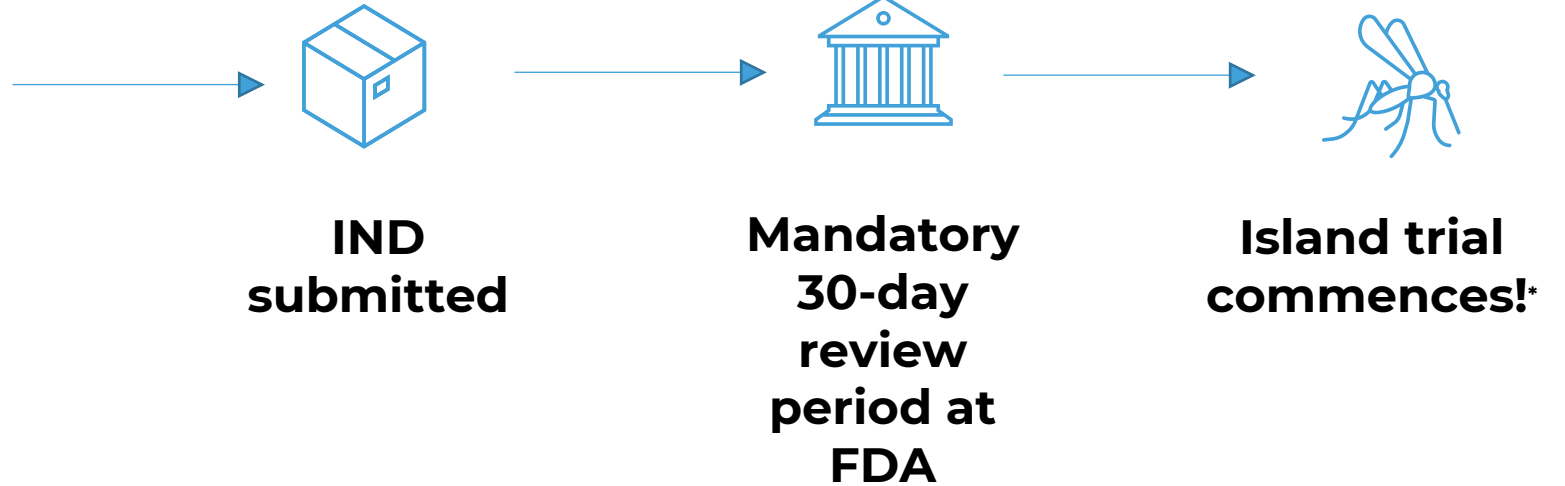
PATHWAY / TIMING TO CLINICAL TRIALS

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

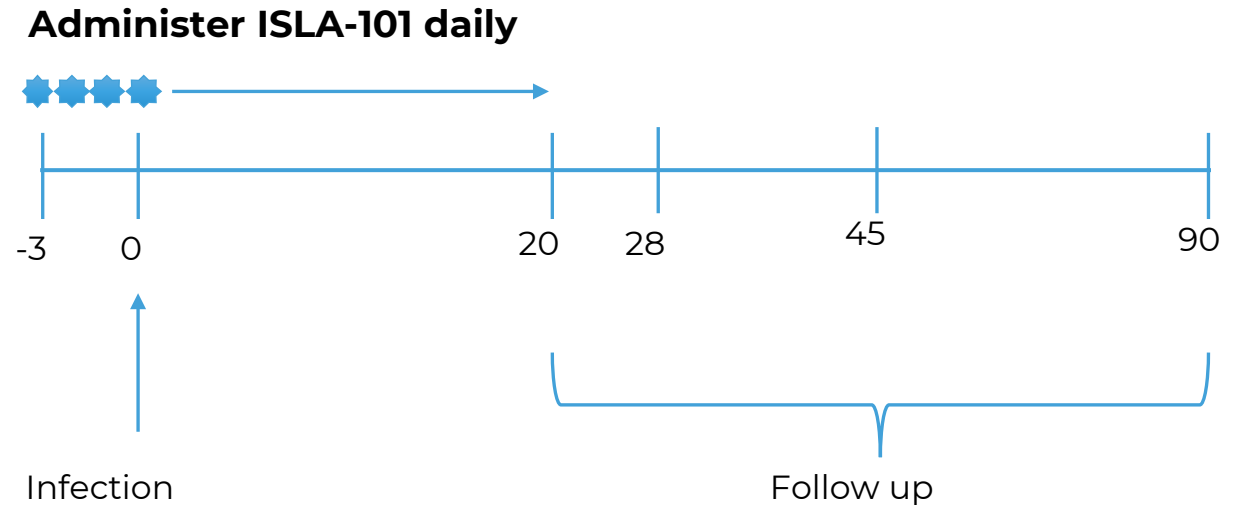
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

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.

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ISLAND
PHARMACEUTICALS
Antiviral therapeutics

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Island Pharmaceuticals
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