# MD PRESENTATION,
# DR DAVID FOSTER, CEO & MD

ISLAND
PHARMACEUTICALS
Antiviral therapeutics

# DISCLAIMER

ISLAND PHARMACEUTICALS
Antiviral therapeutics

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.

# UPCOMING MILESTONES

ISLAND PHARMACEUTICALS
Antiviral therapeutics

## H1 FY 2022

- ✓ Sign SUNY CTA
- ✓ Announce Principal Investigator
- Engage CRO
- API manufacturing
- Advance research collaboration

## H2 FY 2022

- Complete clinical product
- File IND
- Open IND
- Screening subjects for PEACH* trial
- First subject in PEACH trial
- Advance through PEACH cohorts
- Screening libraries in research collaborations

## H1 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.

# ISLAND AT A GLANCE

ISLAND PHARMACEUTICALS
Antiviral therapeutics

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

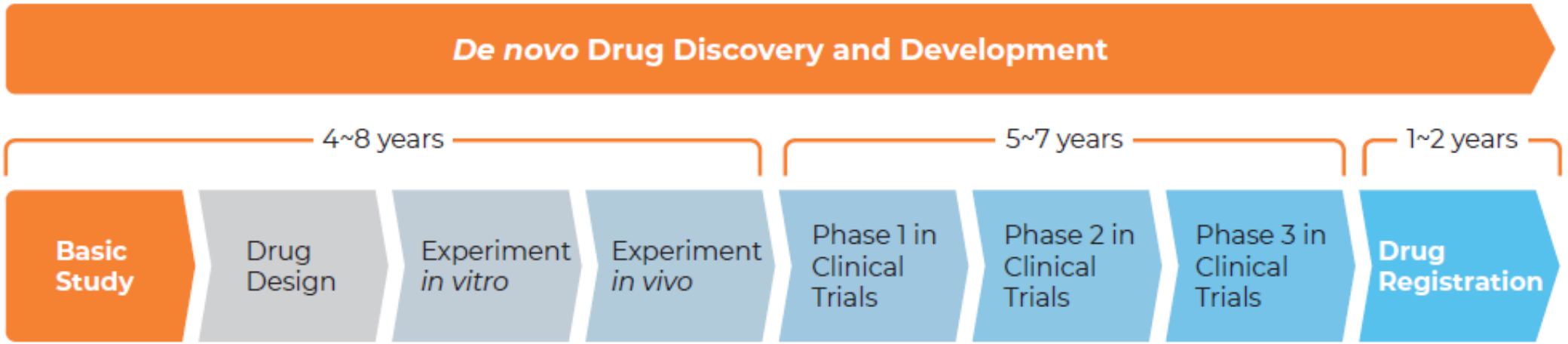
Island Pharmaceuticals lists on the ASX following oversubscribed A$7.5m IPO in April 2021

Island's drug repurposing strategy enables rapid and efficient development of antiviral therapies

Initial focus is on mosquito borne diseases with a Phase II lead program in Dengue fever.

# THE BENEFITS OF DRUG REPURPOSING

ISLAND PHARMACEUTICALS
Antiviral therapeutics




**_De novo_ Drug Discovery and Development**
- Low Success Rate
- Huge Cost and Time-consuming Development

**Drug Repurposing**
- Known Drug Safety
- Reduced Pharmacokinetic Uncertainty

# ISLA-101 REPURPOSED DRUG

## DRAMATICALLY REDUCES DEVELOPMENT TIME, RISK AND COST

ISLAND PHARMACEUTICALS
Antiviral therapeutics

**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**

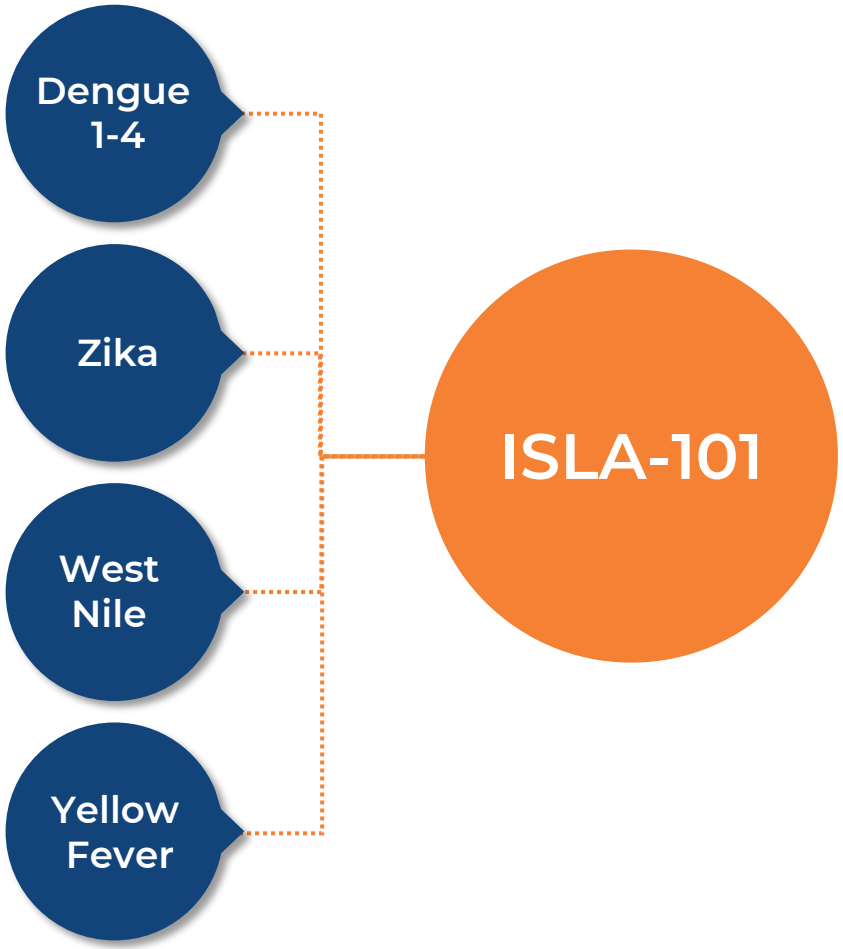
Clearance of early phases allows many years to be saved in drug development and quick path to market

**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

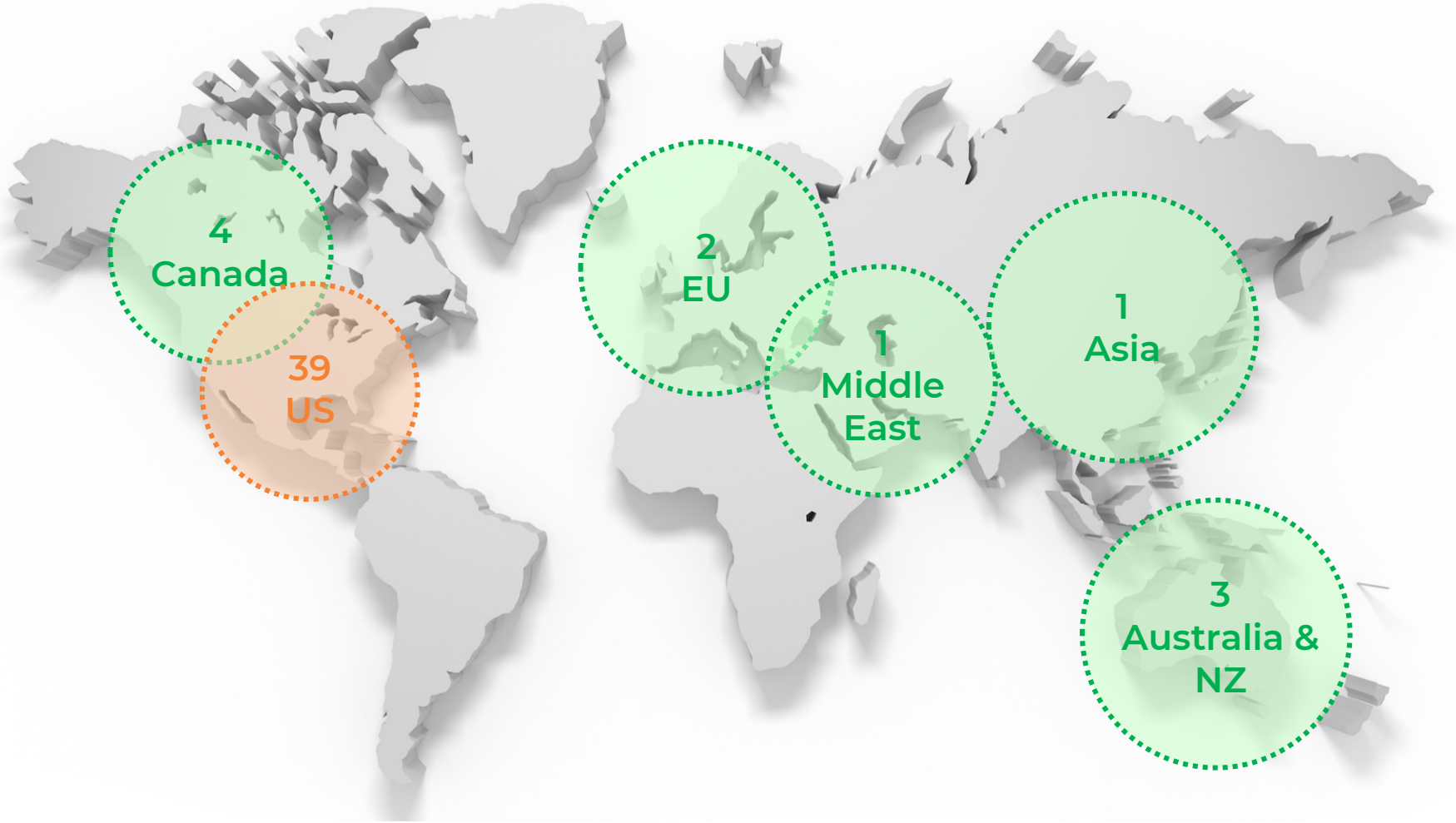
## DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES IN MULTIPLE MODELS OF INFECTION




- 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

# SAFETY PROFILE OF DRUG ESTABLISHED

## 45 HUMAN CLINICAL STUDIES OF ISLA-101 COMPLETED IN OTHER INDICATIONS




Verified as safe in humans by multiple regulators in other clinical indications

# PHASE II DENGUE (PEACH) TRIAL STUDY IN DETAIL

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

**Exclusion**

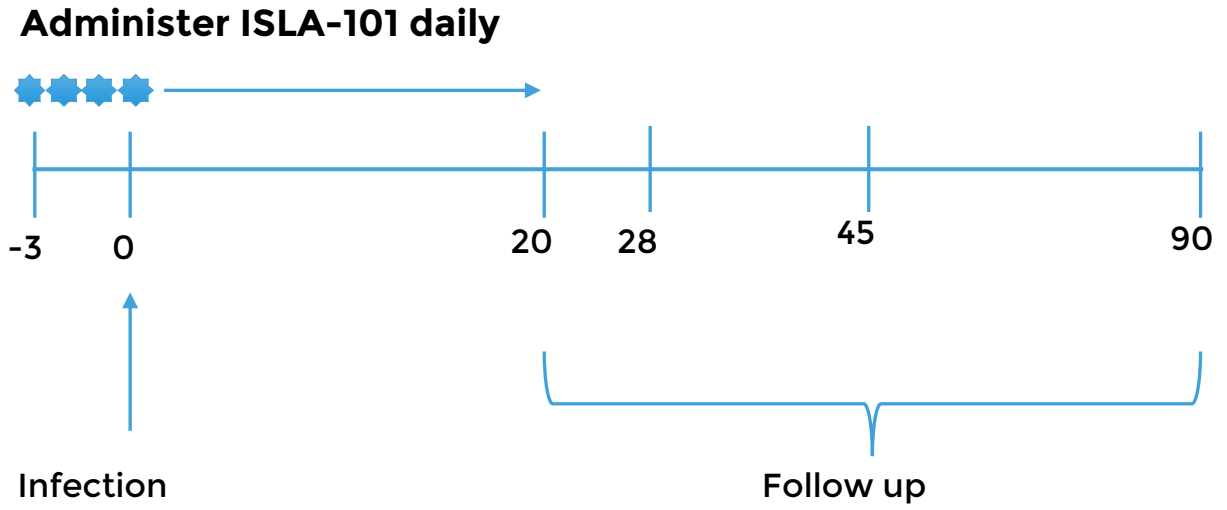
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

**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





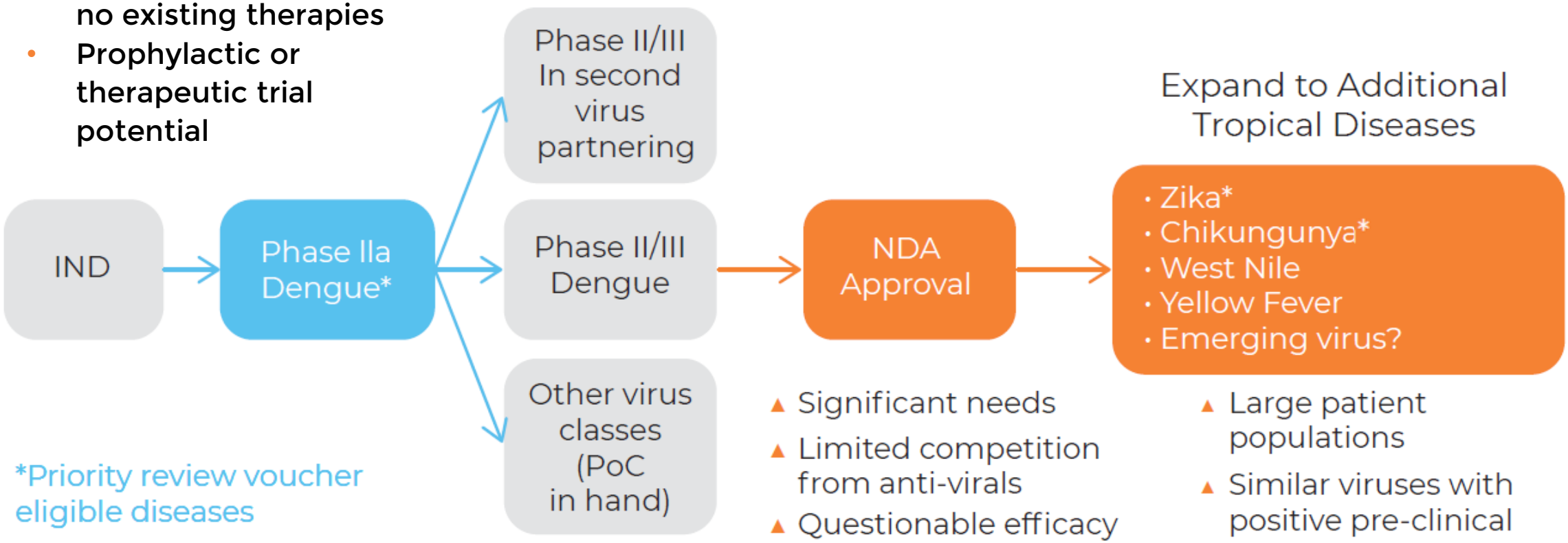
The study will be run at SUNY Upstate Medical University Syracuse, New York

# PLATFORM STRATEGY: MULTIPLE SHOTS ON GOAL

ISLAND PHARMACEUTICALS
Antiviral therapeutics

## TARGETS

- Tropical diseases with no existing therapies
- Prophylactic or therapeutic trial potential




*Priority review voucher eligible diseases

# PRIORITY REVIEW VOUCHER ELIGIBILITY

ISLAND PHARMACEUTICALS
Antiviral therapeutics

- ISLA-101 is eligible for Neglected Tropical Disease designation for the treatment of dengue fever
- This designation means ISLA-101 has the opportunity to be awarded a Priority Review Voucher (PRV) from the FDA if first approved for dengue fever or Zika
- A PRV grants the holder an accelerated six month review of a drug application by the FDA
- As PRVs are transferable, they are highly valuable to drug development companies with numerous precedents for sales to biotech and pharma companies

**The last 10 PRV acquisitions**

| Date | Acquired by | Value |
|---|---|---|
| Q3 2019 | Astra Zeneca | US$95m |
| Q4 2019 | Confidential | US$95m |
| Q1 2020 | Vifor Pharma | US$111m |
| Q3 2020 | Merck | US$100m |
| Q4 2020 | Abbvie | US$95m |
| Q4 2020 | United Therapeutics | US$105m |
| Q1 2021 | Alexion | US$100m |
| Q3 2021 | Kedrion S.p.A | US$105m |
| Q1 2022 | Undisclosed | US$105m |
| Q1 2022 | Albireo | US$105m |
| Average | | US$101.6m |

# COMMERCIAL OPPORTUNITY

ISLAND PHARMACEUTICALS
Antiviral therapeutics

Prophylactic for travelers

Military

National outbreaks

Government Stockpiles

Priority Review Voucher

**Tropical area travellers opportunity:**

- Annual market many millions of individuals (military opportunity not included)
- Predictable outbreaks will drive sales
- 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

# MONASH UNIVERSITY COLLABORATION

## INITIAL LICENSE FOR LEAD PROGRAM AND PIPELINE EXPANSION

ISLAND PHARMACEUTICALS
Antiviral therapeutics

**Monash University**

- Isla US initially licensed intellectual property (IP) created by Monash University. IP was produced as part of a research project undertaken by Monash University that led to a drug candidate, ISLA-101 for repurposing. ISLA-101 is indicated for the prevention and/or treatment of mosquito borne viruses.
- Prof. David Jans at Monash Biomedicine Discovery Institute focusses on viruses of medical significance, seeking to explore virus-human protein interactions in disease, and how this can be exploited for therapeutic intervention.
- Our expanded collaboration with Prof. David Jans underpins our pipeline development strategy to pivot quickly to develop drugs as urgent emerging viral disease issues arise again.

MONASH University

**Prof. David Jans**

# GRIFFITH UNIVERSITY COLLABORATION

## BOOST PIPELINE DEVELOPMENT

ISLAND PHARMACEUTICALS
Antiviral therapeutics

On the 23 August 2021
**Island Pharmaceuticals (ASX: ILA) announced a Anti-Viral Molecule Screening Collaboration with Griffith University.**

- The new drug research collaboration focuses on repurposing small molecules with known clinical histories as new anti-viral agents.
- Using the small molecule libraries at Griffith Institute for Drug Discovery (GRIDD) and Compounds Australia facility, using highly sensitive assays.
- Utilises highly sensitive screening technology to assist in accelerating drug repurposing strategies
- Enhances Island's drug development pipeline, focused on advancing preventative or therapeutic drugs for existing and emerging viral threats beyond mosquito borne viruses

Griffith UNIVERSITY
Griffith Institute for Drug Discovery

**Prof. Ron Quinn**
**Griffith University**

MENZIES HEALTH INSTITUTE QUEENSLAND
Griffith UNIVERSITY

**Prof. Suresh Mahalingam**
**Health Institute Queensland (MHIQ)**

# DRUG DEVELOPMENT PIPELINE

ISLAND PHARMACEUTICALS
Antiviral therapeutics

| Program | Indication | Stage of Development | | | | |
|---|---|---|---|---|---|---|
| | | Preclinical | Phase I | Phase 2 | Phase 3 | FDA Review |
| ISLA-101 | Dengue (PEACH) | | | To be initiated | | |
| | Other mosquito (or vector) borne diseases | | | | | |
| Monash Collaboration | TBD | | | | | |
| Griffith Collaboration | TBD | | | | | |

# KEY COLLABORATIONS & ALLIANCES

## SUPPORTING FUTURE PIPELINE DEVELOPMENT

ISLAND PHARMACEUTICALS
Antiviral therapeutics

| | |
|---|---|
| MONASH University | 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 |
| Griffith UNIVERSITY Griffith Institute for Drug Discovery | 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. |
| COMPOUNDS AUSTRALIA | Research collaboration agreement signed with Australia's largest drug library containing approximately four and a half thousand molecules that can be searched for drug re-purposing and pipeline development |
| UNITED STATES ARMY | Cooperative Research and Development Agreement (CRADA) with the US Army in preparation for its Phase II clinical study for ISLA-101 |
| Catalent | Supply agreement with Catalent for manufacture of Fenretinide softgels for dengue fever trial participants |
| NIH NATIONAL CANCER INSTITUTE | Right to reference National Cancer Institute IND for Isla-101 |

# BOARD, MANAGEMENT & SCIENTIFIC BOARD

ISLAND PHARMACEUTICALS
Antiviral therapeutics

ISLAND IS LED BY A HIGHLY CAPABLE, EXPERIENCED MANAGEMENT TEAM, BOARD OF DIRECTORS AND SCIENTIFIC ADVISORY BOARD WITH EXTENSIVE EXPERTISE IN DRUG REPURPOSING AND DEVELOPMENT, INFECTIOUS DISEASES AND EXECUTING SUCCESSFUL COMMERCIAL TRANSACTIONS.

## MANAGEMENT TEAM & BOARD OF DIRECTORS

**Dr. Paul MacLeman**
**Executive Chair**

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

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

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

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

## SCIENTIFIC ADVISORY BOARD

**Assoc. Prof. Leigh Farrell**

**Prof. Stephen Thomas MD**

**Dr. Simon Tucker**

# KEY STRENGTHS

ISLAND PHARMACEUTICALS
Antiviral therapeutics

**Initially targeting dengue diseases with unmet need**

Targeting diseases, starting with dengue fever, with a significant unmet medical need and growing economic burden

**Drug repurposing strategy**

Repurposing can save tens of millions of dollars and up to a decade of development time usually required to commercialise a new drug

**Phase II ready asset**

Lead compound, ISLA-101, has been in 45 clinical trials demonstrating an excellent safety profile in thousands of patients

**Commercial upside**

Potential 'platform in a pill' to treat tropical diseases. Approval of ISLA-101 by the US FDA could see company claim a Priority Review Voucher

**Pipeline expansion strategy**

Research collaboration agreements in place with Monash University and Griffith University to expand anti-viral pipeline

**Highly experienced team**

Experienced Board, Management Team & Scientific Advisory Board with extensive expertise in drug repurposing, infectious diseases and commercial transactions


David Foster
Chief Executive Officer & Executive Director
david@islapharma.com

www.islapharma.com
Registered office: Suite 201, 697 Burke Rd, Camberwell VIC 3124, Australia
Approved for release by Paul MacLeman

Island Pharmaceuticals Limited
ACN 641 183 842