



**ISLAND**

PHARMACEUTICALS

Antiviral therapeutics

**SOLVING URGENT  
VIRAL DISEASE  
THREATS**

**IPO Roadshow (ASX: ILA)  
April 2021**



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# INTRODUCTION



**ISLAND**

PHARMACEUTICALS

Antiviral therapeutics



# ISLAND SNAPSHOT

BRINGING ITS PLATFORM IN A PILL TO MARKET



Island has repurposed ISLA-101, an antiviral oral drug to treat mosquito-borne viruses (eg dengue fever / Zika) and intends to complete Phase II studies with a significantly de-risked clinical program

Warming global climates are accelerating the presence of mosquito-borne viruses that can cause deaths in the US, Europe and Australia

# KEY STRENGTHS



**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**

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



**Phase II ready asset**

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



**Promising results to date**

Results in aggressive animal and human cellular models of dengue fever and Zika infections as well as data in a range of other flaviviruses



**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

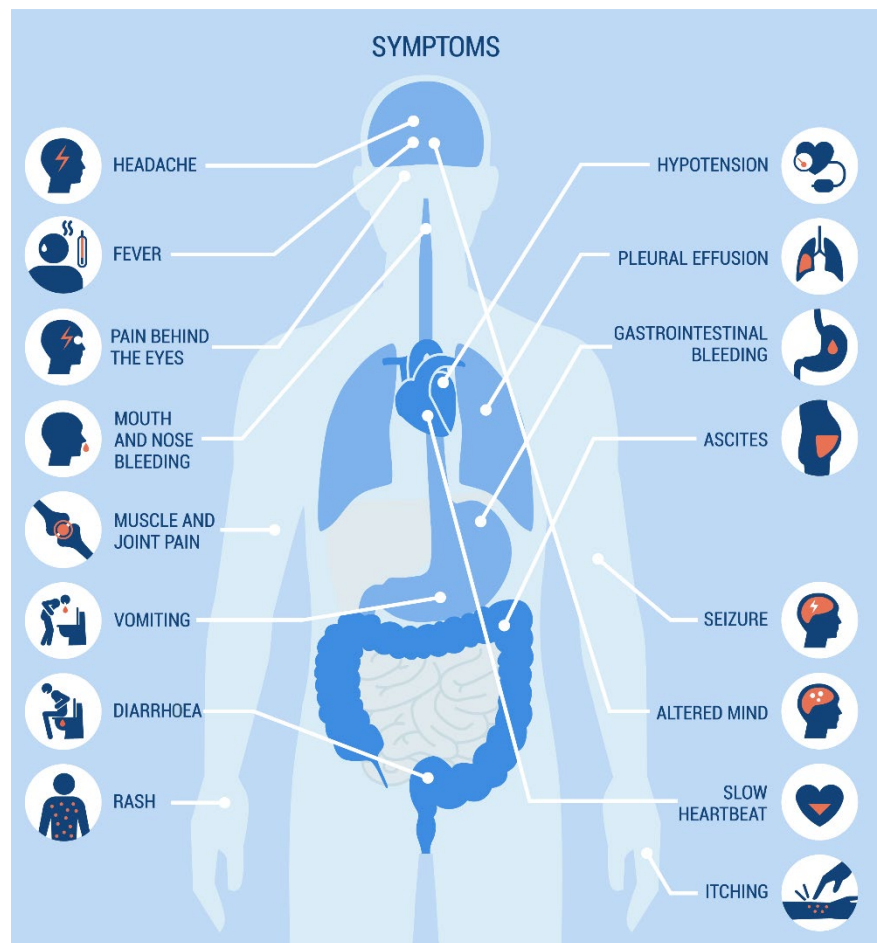


**Highly experienced team**

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

# WHY DENGUE DISEASES?

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 spring board into other viral diseases

Priority Review Voucher eligibility



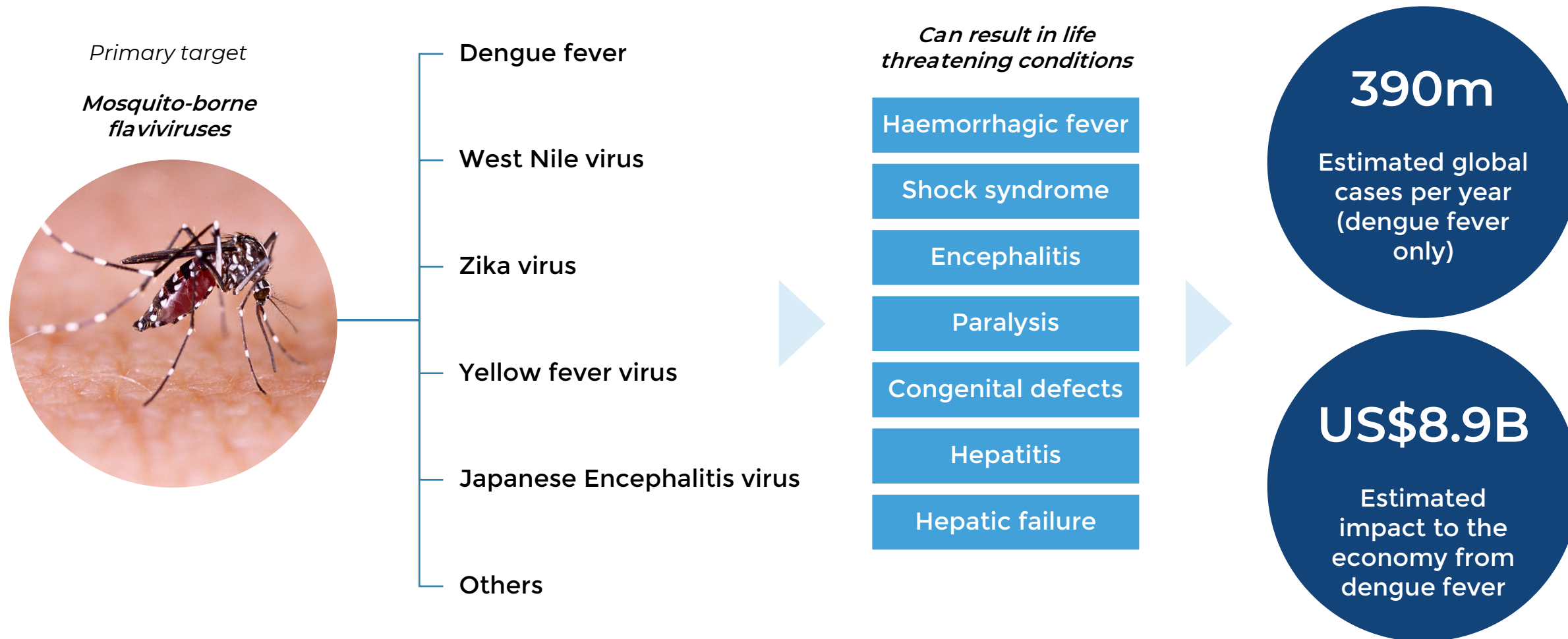
# INDUSTRY & MARKET





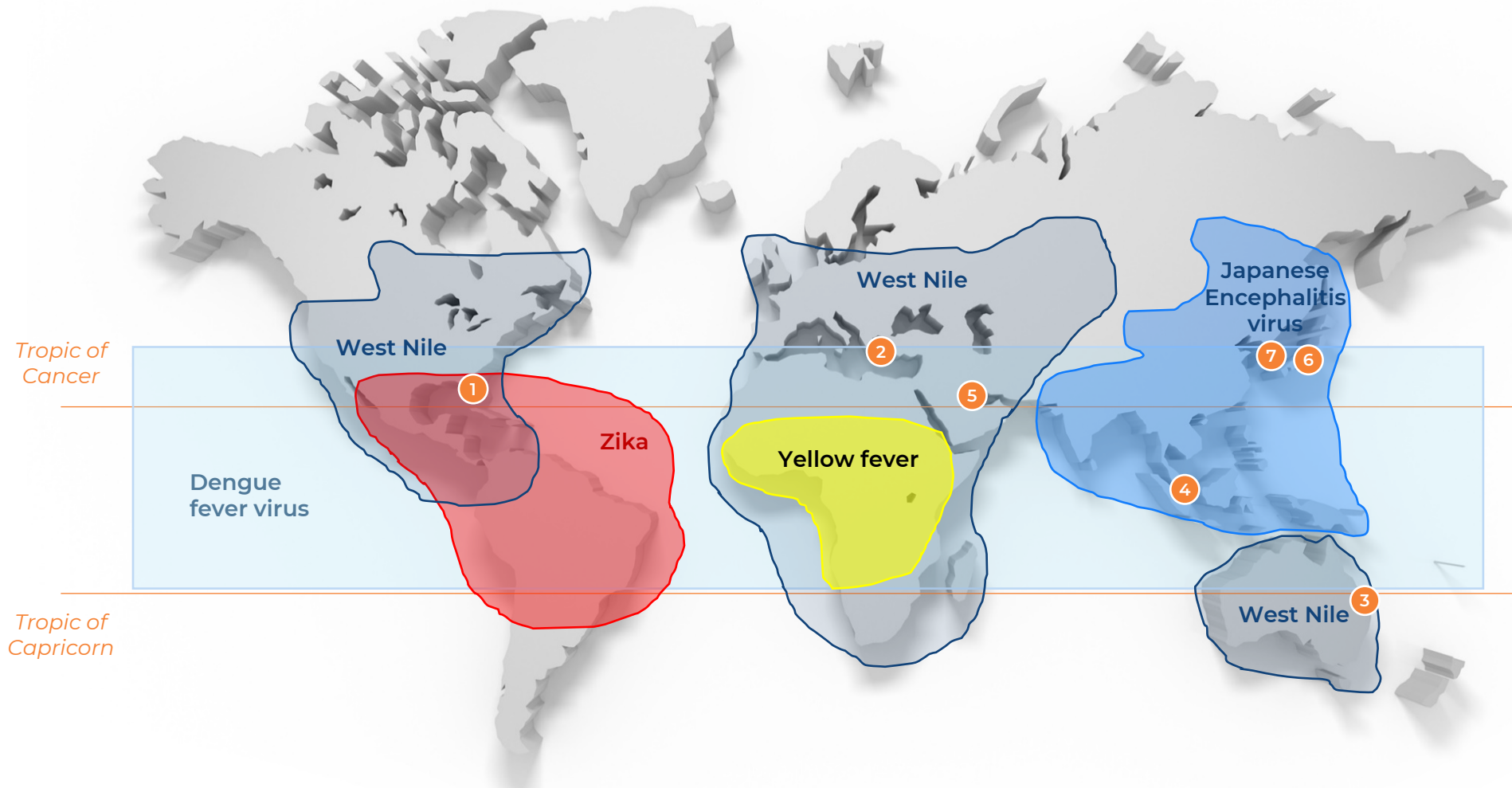
# MOSQUITO BORNE DISEASES

MORE PATIENTS, HIGH COSTS, POTENTIALLY A LIFETIME OF ISSUES



# FLAVIVIRUSES BECOMING GLOBAL

WARMING GLOBAL CLIMATES ARE EXPANDING SPREAD BEYOND THE TROPICS



Flaviviruses are spreading outside the tropics:

- 1 Florida, US
- 2 Mediterranean, EU
- 3 QLD, Australia

Growing issue for countries hosting US military bases

- 4 Singapore
- 5 Saudi Arabia
- 6 Japan
- 7 South Korea



# LIMITED AVAILABLE SOLUTIONS

## HIGHLY PREVALENT DISEASES WITH UNMET MEDICAL NEED

		Dengue fever	West Nile	Zika Virus	Yellow fever	Japanese Encephalitis	
	 Worldwide prevalence	390 million	n/a	Up to 1.5 million	130,000	70,000	→ Viral diseases are a leading cause of hospitalisation and death
	 Effective drug therapy	No	No	No	No	No	→ Antimalarial drugs market is expected to reach US\$1B in 2026 providing guidance to potential market size
	 Vaccine	Limited	No	No	Limited	Limited	→ Vaccine development potentially can exacerbate symptoms from infections by different strains

# COMPANY OVERVIEW





# 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



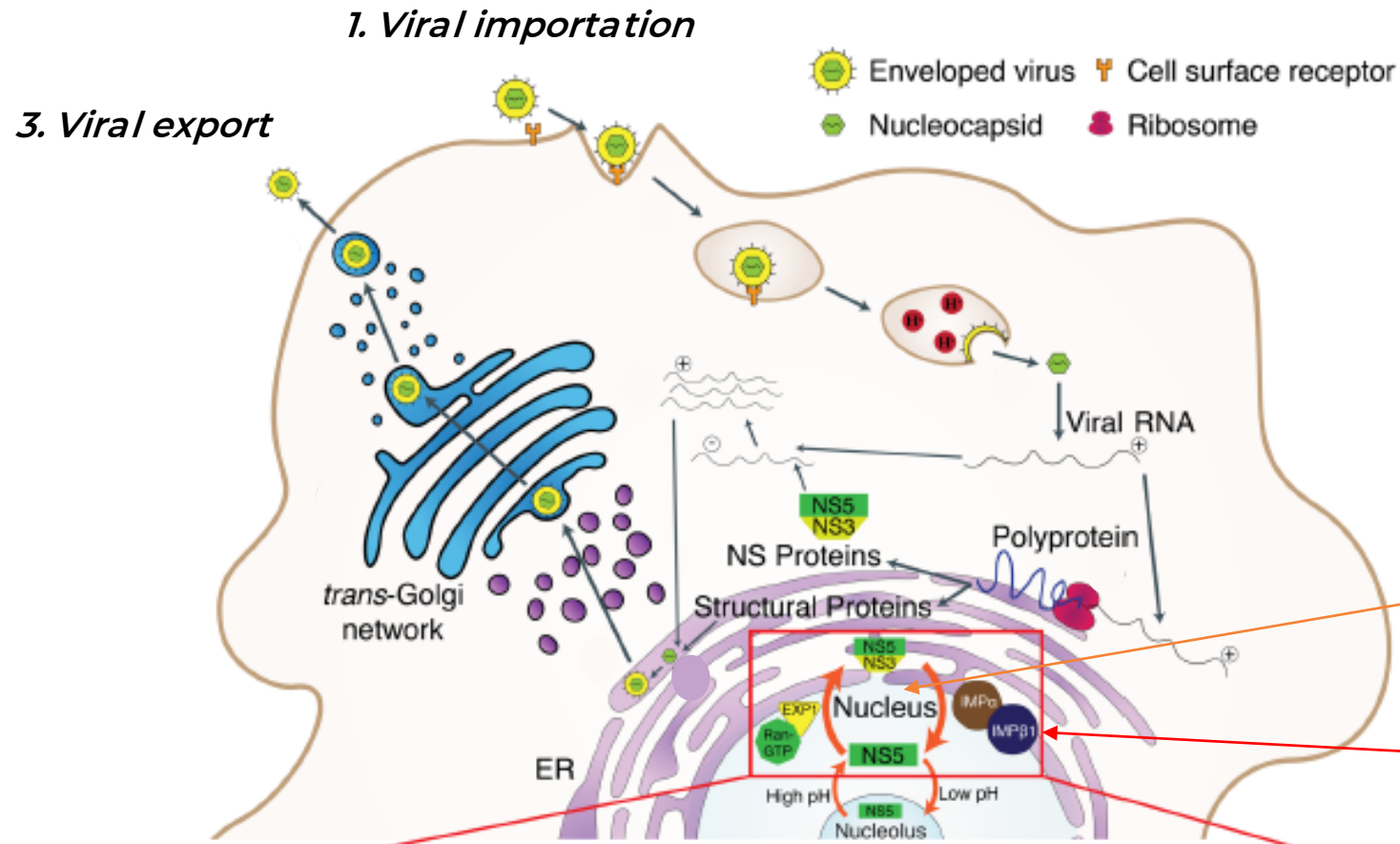
Clearance of early phases allows many years to be saved in drug development and quick path to market



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

# ISLA-101 PREVENTS VIRAL REPLICATION

## ISLA-101 INHIBITS PROPAGATION OF FLAVIVIRUSES



- To replicate, the virus needs to hijack the nucleus of the host cell
- Studies demonstrated ISLA-101 prevents this so prevents virus replication
- Same mechanism of action for a therapeutic or prophylactic – either before or after exposure to the virus

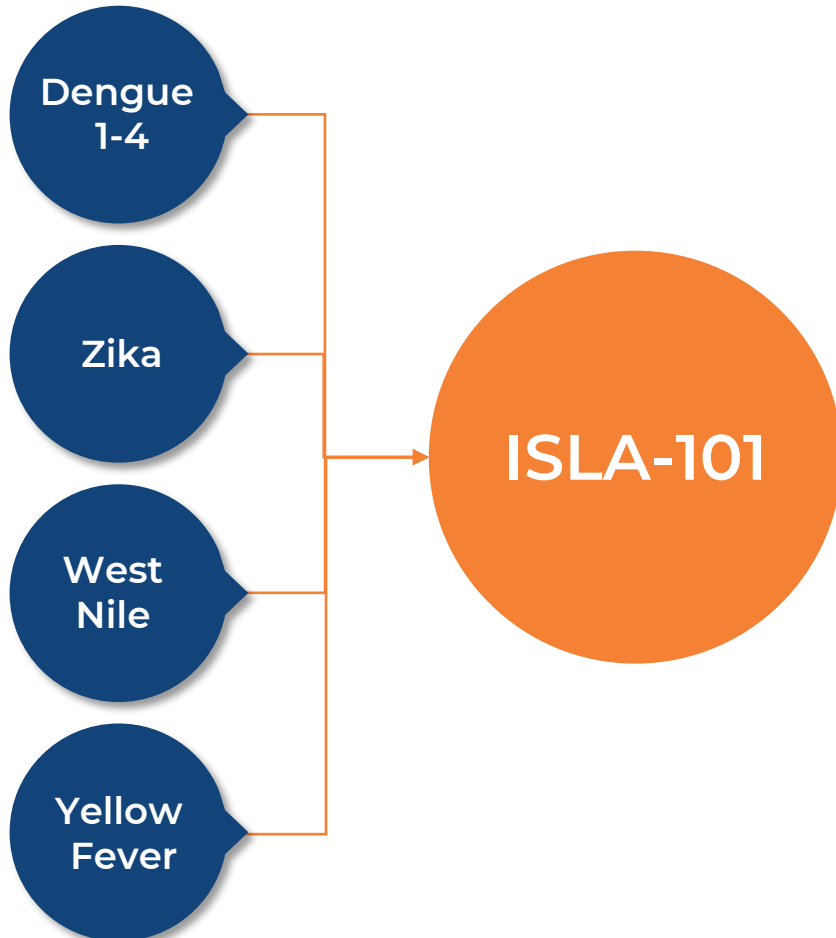
**ISLA-101 targets protection of the nucleus**

**2. Viral replication**



# ISLA-101 BROAD ACTIVITY EVIDENT

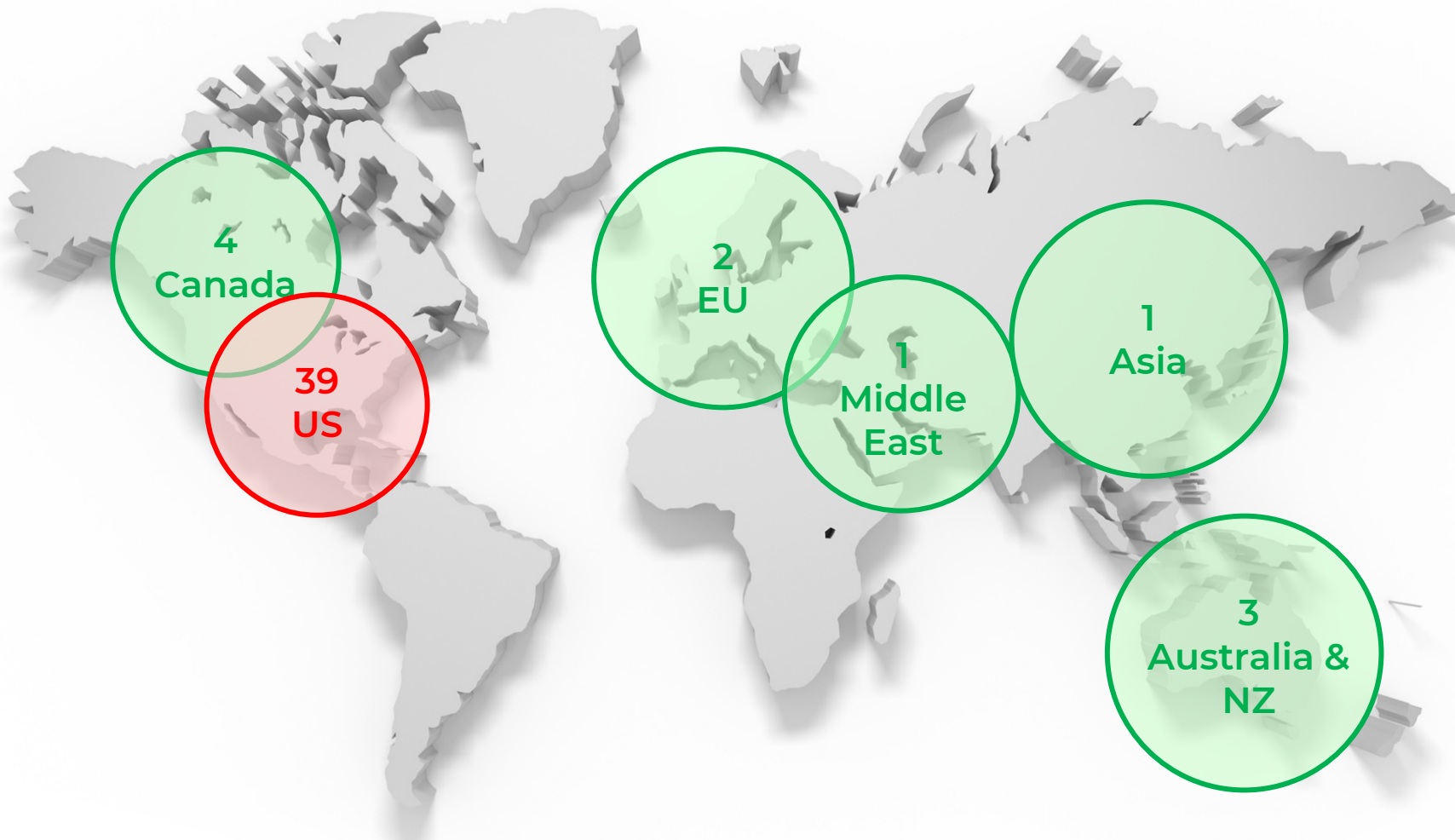
DEMONSTRATED ACTIVITY AGAINST FLAVIVIRUSES IN FRESH HUMAN CELLS



- 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

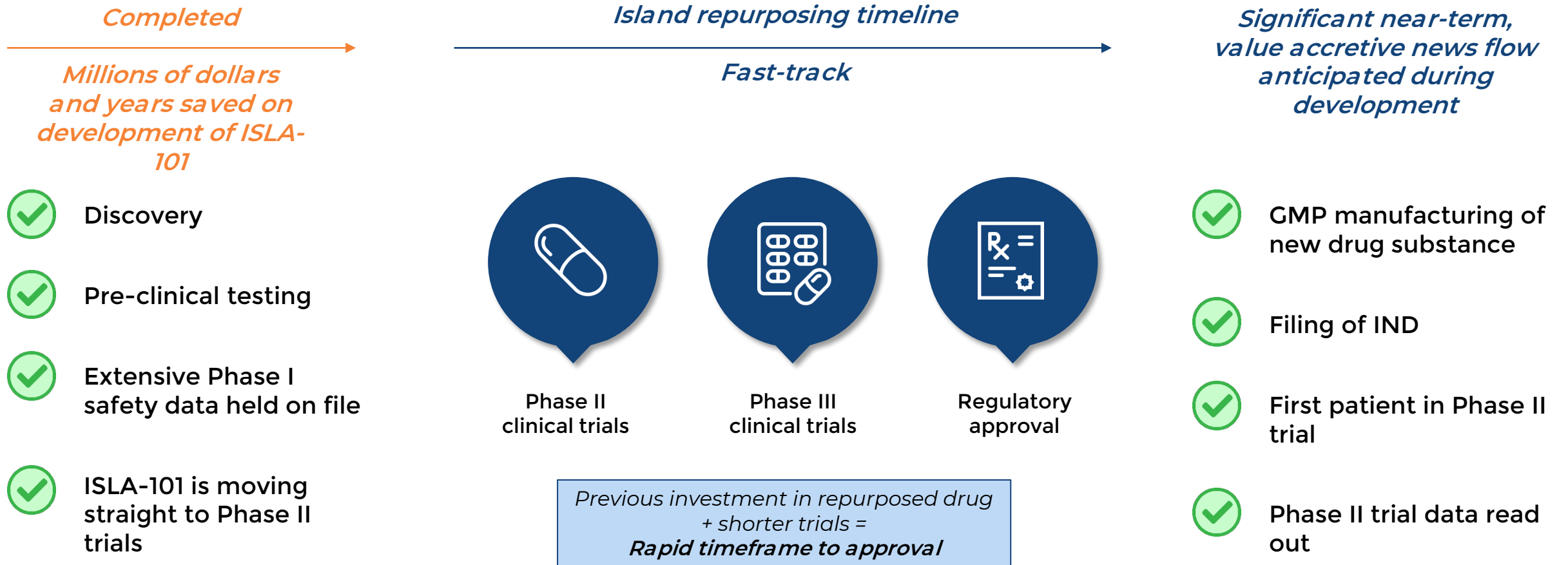


Verified as safe in humans by multiple regulators in other clinical indications



# ACCELERATED TIME TO APPROVAL

LEVERAGING THE ESTABLISHED SAFETY PROFILE OF ISLA-101



# PHASE II CHALLENGE STUDY

## AN EFFICIENTLY STRUCTURED TRIAL, LEVERAGING CRADA CONTROL DATA

### 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

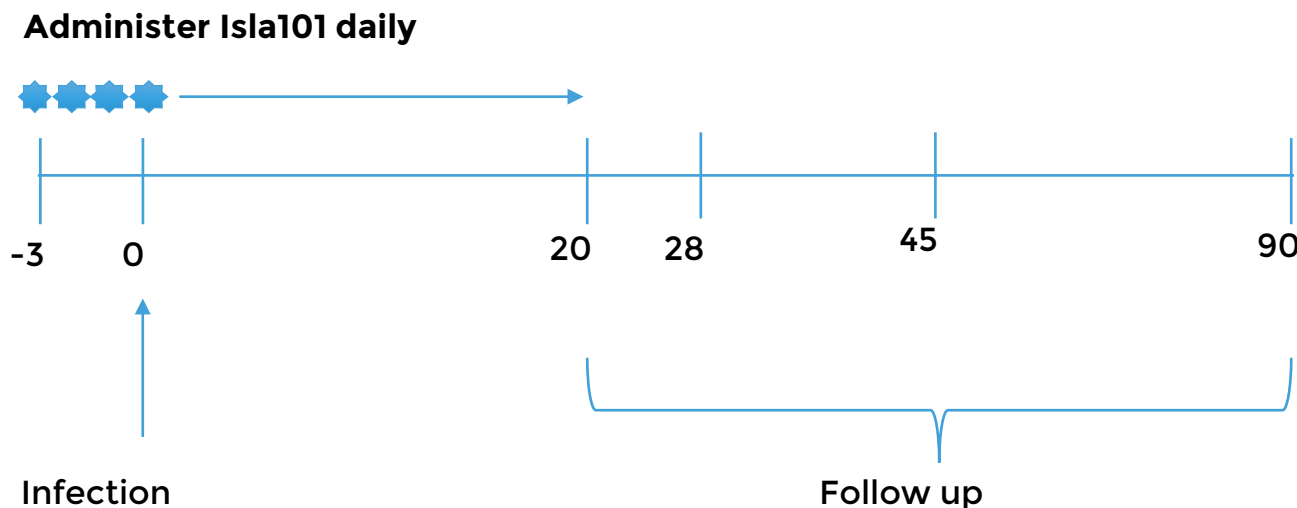
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease
- Others

#### 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

- Characterize 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

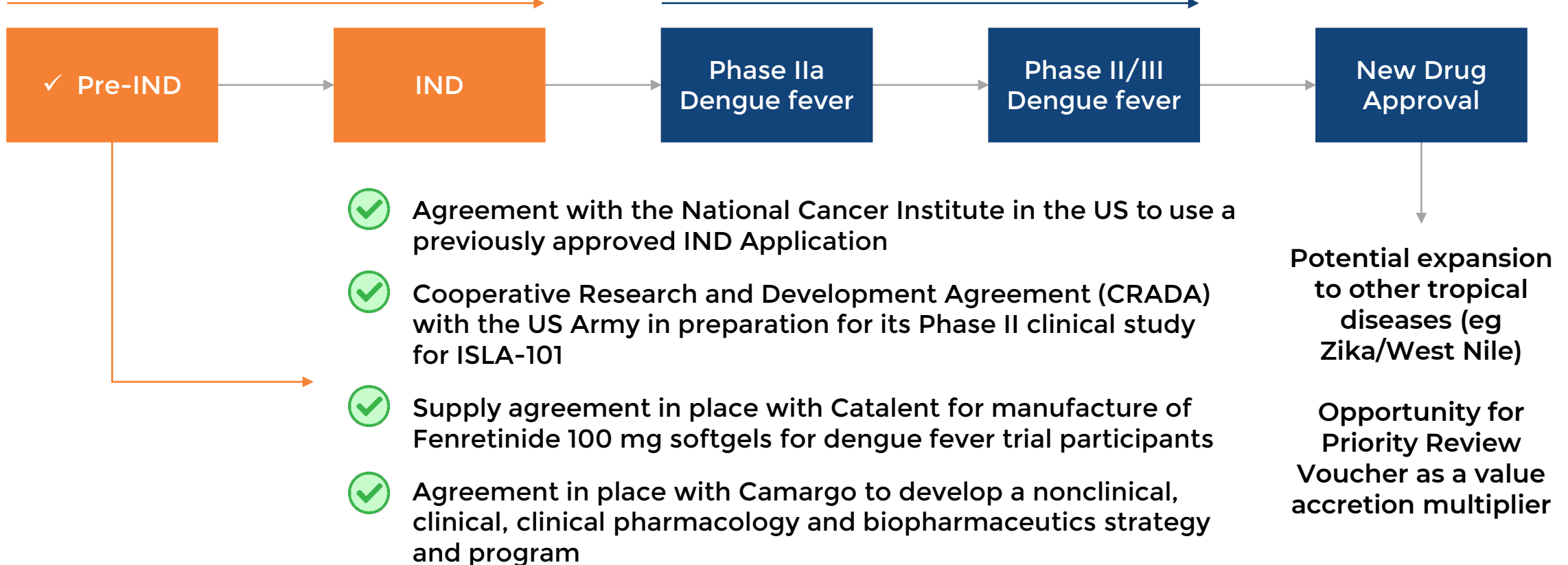


# CLINICAL DEVELOPMENT PROGRAM

INITIAL FOCUS ON BRINGING A DENGUE FEVER DRUG TO MARKET

Activities to derisk Island's Investigational New Drug (IND) application

Shortened timeframe for Phase II trials





# PRIORITY REVIEW VOUCHER ELIGIBILITY

## ISLA-101 INHIBITS THE STAGES AND PROTEINS OF FLAVIVIRUSES

- 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

### *Recent PRV acquisitions*

Date	Acquired by	Value
Q2 2018	Gilead	US\$81m
Q4 2018	Eli Lilly	US\$80m
Q1 2019	Biohaven	US\$105m
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
<b>Average</b>		<b>US\$97m</b>

# KEY COLLABORATIONS & ALLIANCES

## SUPPORTING FUTURE PIPELINE DEVELOPMENT

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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

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Potential to access Australia's largest drug library containing approximately four and a half thousand molecules that can be searched for drug re-purposing and pipeline development

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Cooperative Research and Development Agreement (CRADA) with the US Army in preparation for its Phase II clinical study for ISLA-101

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Supply agreement with Catalent for manufacture of Fenretinide softgels for dengue fever trial participants

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Right to reference National Cancer Institute IND for Isla101

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In-licensed patents	<ul style="list-style-type: none"><li>• PCT/AU2014/050017, filed 16 April 2014</li><li>• National stage applications underway/filed in Australia, Brazil, Canada, Singapore &amp; US</li><li>• Issued patents in Australia, Brazil and Singapore</li><li>• Potential for new patents</li></ul>
Available knowhow	<ul style="list-style-type: none"><li>• Investigator Brochures from National Cancer Institute and Walter Reed Army Research Hospital</li><li>• Right of cross reference to existing IND from NCI and Walter Reed</li><li>• Rights to Walter Reed control volunteer data</li></ul>
New IP	<ul style="list-style-type: none"><li>• Likely identify inventions to patent during clinical trials to expand Island Pharma portfolio</li></ul>
Licenses	<ul style="list-style-type: none"><li>• Monash license</li><li>• Single digit royalties, deferred milestones until Phase III</li></ul>
New leads	<ul style="list-style-type: none"><li>• Research collaboration program</li></ul>

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# KEY PEOPLE



# BOARD OF DIRECTORS



**Dr. Paul MacLeman**  
Executive Chair

- Decades of experience across the life sciences sector, including veterinary practice, pharmaceutical development and manufacturing, biotechnology, diagnostics and finance.
- Expertise in capital raising, business development, technology commercialisation, and drug development. He has founded life sciences start-ups in the biologics area and worked in investment banking.
- Previously served as Managing Director and/or CEO of several VC funded, ASX, NASDAQ and TSX listed companies. Paul is the current Chairman of AdAlta Limited (ASX:IAD). Fellow of the Australian Institute of Company Directors.



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

- 20+ years experience in life sciences representing pharmaceutical, biotherapeutic and diagnostic companies, while in private legal practice.
- Served as intellectual property counsel at Medarex, a mid-sized biotherapeutics company, acquired by Bristol-Myers Squibb.
- Co-founded Roberts Foster LLP - a technology focused law firm, bionorthTx- a regional life science trade association, and multiple private biotechnology companies.
- Board member of bionorthTx and private biotechnology companies, and is a Member of Australian Institute of Company Directors.
- Ph.D. from The University of Texas Southwestern Medical Center and J.D. from Golden Gate University School of Law.



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

- Chair of Medicines Australia; previously CEO and Executive Director of AusBiotech Ltd. and the Australian Red Cross. Director, Research Australia, the Agricultural Biotechnology Council of Australia and the Advisory Board for the School of Biological Sciences at Monash University.
- Chaired, or has been a member of various Federal and State government advisory committees. PhD in Genetics from the University of Melbourne, and is a Fellow of the Australian Academy of Technological Sciences and Engineering.



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

- Managing Partner. KESA Partners. Decades of experience in healthcare and investment, including Managing Director of Signet Healthcare Partners, serving on investee companies as Chairman, Director and Interim CEO of pharmaceutical companies and CROs.
- Substantial senior investment banking experience at firms such as Darby Overseas Investments, Dillon Read and E. F. Hutton. Former Director - Corporate Finance US Treasury, and retired Captain, U.S Army Special Forces.



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

- Extensive experience in the health and biotechnology industries, including Board positions in numerous ASX listed biotechnology companies, Chairman of genomics solutions company, RHS Ltd, which was acquired by PerkinElmer Inc. Recently successfully exited Better Medical group, of which he was previously Non-Executive Chairman.
- Currently a Non-Executive Director of Factor Therapeutics (ASX: FTT) and of Anataira Lifesciences Ltd (ASX:ANR).
- MBBS (Adelaide), Fellow of the Australian College of Rural and Remote Medicine and a Fellow of the Australian Institute of Company Directors.



# SCIENTIFIC ADVISORY BOARD

## HEAVYWEIGHT ADVISORS WITH GLOBAL PEDIGREE



**Assoc. Prof. Leigh Farrell**

- Former Vice President of Business Development at Biota Pharmaceuticals (now Vaxart)
- Extensive operational and advisory experience in antiviral drug development including for the military
- Previously Chief Operating Officer, d3 Medicine, General Manager then CEO, GeneShears Pty Ltd; Research Manager Johnson & Johnson Research Pty Ltd; Associate Director, GBS Venture Partners
- Member, the Australian Research Advisory Council and the Victorian Biotechnology Advisory Council



**Dr. Simon Tucker**

- Former Vice President of Research at Biota Pharmaceuticals (now Vaxart), where he was responsible for their entire intellectual property and research portfolio and oversaw the development of the now FDA approved influenza drug Relenza, one of only three anti-virals for influenza
- Decades of experience in pharmaceutical research and development and management as CEO of both Jumpstart Fertility Inc. and Continuum Biosciences Inc
- Previously worked at GD Searle, USA, helping make key discoveries leading to the development of a treatment for HIV infection



**Prof. Stephen Thomas MD**

- International leadership role as Lead Principal Investigator for Pfizer/BioNTech global Phase III COVID-19 vaccine trial now being deployed globally
- Prof. Thomas is a world-renowned virologist and vaccinologist and has authored numerous papers and articles on dengue fever, Zika and many other infectious diseases
- Chief, Division Of Infectious Diseases, New York Upstate Medical University; Professor of Medicine, Professor of Microbiology & Immunology, and Infectious Diseases physician-scientist from the State University of New York (SUNY), Upstate Medical University; Chief, Division of Infectious Diseases and Director, Institute for Global Health and Translational Science (IGHTS)
- Twenty years in the U.S. Army Medical Corps serving at the Walter Reed Army Institute of Research (WRAIR)



# DETAILS OF THE OFFER



# KEY OFFER INFORMATION

## Offer Summary\*

Offer Price per Share	\$0.25
Number of Shares available under the Offer	30,000,000
Gross proceeds from the Offer to the Company	\$7,500,000
Number of Shares on issue at IPO	50,968,466
Total number of Shares on issue on completion of the Offer	80,968,466
Market capitalisation on completion of the Offer	\$20,242,116

\* Please refer to the Prospectus, dated 26 February 2021, for further details on the Offer, capital structure and use of funds

# USE OF FUNDS

Use of funds*	A\$ ('000)	% of funds
Clinical, regulatory and implementation of proposed ISLA-101 development- Phase II study	\$3,478,000	46.4%
Intellectual property, and research and development	\$699,390	9.3%
Formulation development	\$455,000	6.1%
Working Capital	\$2,417,610	32.2%
Expenses of the Offer	\$450,000	6.0%
<b>Total uses</b>	<b>\$7,500,000</b>	<b>100.0%</b>

- Perform a Phase II clinical study on ISLA-101
- Formulation development for commercial and follow on products
- Additional product pipeline development
- Fund working capital requirements

\* Please refer to the Prospectus, dated 26 February 2021, for further details on the Offer, capital structure and use of funds



# IMPORTANT DATES\*

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Prospectus lodgement	Friday 26 February 2021
Offer period opens	Monday 8 March 2021
Offer period closes	Monday 29 March 2021
Settlement of the Offer and Allocation of Shares	Friday 2 April 2021
Despatch of holder statements	Tuesday 6 April 2021
Expected commencement of trading on the ASX	Tuesday 13 April 2021

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\* Note this timetable is indicative only and is subject to change without notice

# Island Pharmaceuticals Limited

ACN 641 183 842

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David Foster  
Chief Executive Officer & Executive Director  
[david@islapharma.com](mailto:david@islapharma.com)

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