**8 May 2025**

ASX Announcement

# US non-deal roadshow presentation

**MELBOURNE Australia, 6 May 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; Island or the Company) is pleased to provide the attached copy of the Company's latest investor presentation, which will be used as part of an upcoming US non-deal roadshow.

Island advises that CEO and Managing Director, Dr David Foster will be undertaking a number of investor meetings in New York from Thursday, 8 May to Friday, 9 May with several US-based institutional investors, family offices and high net-worth individuals.

During meetings, Dr Foster will have the opportunity to provide US investors with a detailed overview of the clinical pathway for the Company's lead asset ISLA-101, prior to the pending release of unblinded results from the Phase 2a/b PROTECT clinical trial utilising ISLA-101 to combat dengue fever. High level results are anticipated later this month. Dr Foster will also provide an update to US investors around the Company's pipeline expansion opportunities, with particular focus on Galidesivir, a broad-acting antiviral molecule.

**CEO and Managing Director**, **David Foster said**: *"We are pleased to commence this roadshow, which has attracted strong interest from a diverse network of sophisticated US investors. We are confident that it will provide the Company with a fantastic opportunity to clearly articulate our value proposition at an exciting phase of our clinical development pathway. I look forward to meetings with a new investor network in New York ahead of the imminent release of our Phase 2a/b PROTECT trial results in the coming weeks."*

- Ends -

***To subscribe to Island's monthly newsletter, IslandWatch, and other forms of email communications, please visit this page of our website.***

**Approved for release to the ASX by:**

David Foster (CEO and Managing Director)
Island Pharmaceuticals Limited
info@islandpharmaceuticals.com

Investors and media, for further information, please contact:

Henry Jordan
Six Degrees Investor Relations
+61 (0) 431 271 538
henry.jordan@sdir.com.au

## About Island Pharmaceuticals

Island (ASX: ILA) is a drug repurposing company, focused on areas of unmet need for antiviral therapeutics to address 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.

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 theCompany's share registry, Automic Registry Services, whose contact info is housed on theShareholder Services page of the Company's website.*

Visit www.islandpharmaceuticals.com for more on Island.

ISLAND PHARMACEUTICALS

Antiviral therapeutics

# COMBATTING URGENT VIRAL DISEASE THREATS

## US NON-DEAL ROADSHOW PRESENTATION

DR DAVID FOSTER, MANAGING DIRECTOR

May 2025

(ASX: ILA)

# 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 an antiviral therapeutics company targeting infectious diseases

Dengue infects up to 400m per year*

Major market potential

Positive results in aggressive models

Phase 2a/b PROTECT clinical trial in dengue underway

Priority Review Voucher potential

Pipeline expansion pending with expedited approval route defined

# CORPORATE OVERVIEW

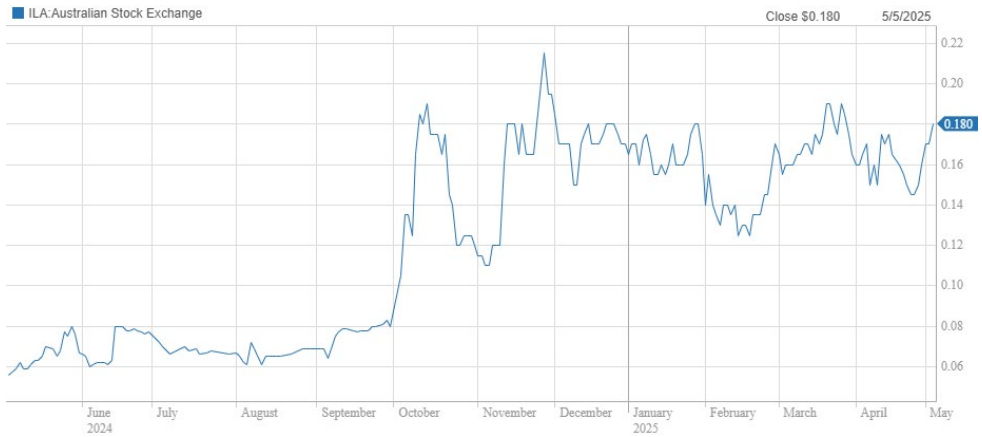


## Snapshot

| | |
|---|---|
| Share on issue[1]: | 210,259,700 |
| Price per share[1]: | $0.18 |
| Market capitalisation[1]: | $37.85m |
| Cash at bank (31 March 2025)[2]: | $4.82m |
| DoD grant funding to directly support the Phase 2a/b PROTECT clinical study | USD $625k |

| **Substantial shareholders** | |
|---|---|
| Dr William James Garner[3] | 15.79% |
| Jason Alan Carroll[4] | 14.73% |
| MWP Partners Limited[5] | 9.94% |
| Dr Daniel Tillett[6] | 6.72% |

## Price & volume (12 month)




## Board of Directors

| |
|---|
| Phil Lynch, Executive Chairman |
| Dr David Foster, CEO and Managing Director |
| Chris Ntoumenopoulos , Non-Executive Director |

1. As at 5 May 2025
2. Does not take into consideration cash used since reporting date
3 Per holding per Substantial interest notices lodged with ASX on 25 March 2025
4. Per holding per Substantial interest notice lodged with ASX on 25 March 2025
5 Per holding per Substantial interest notice lodged with ASX on 21 March 2025
6 Per holding per Substantial interest notices lodged with ASX on 26 March 2025

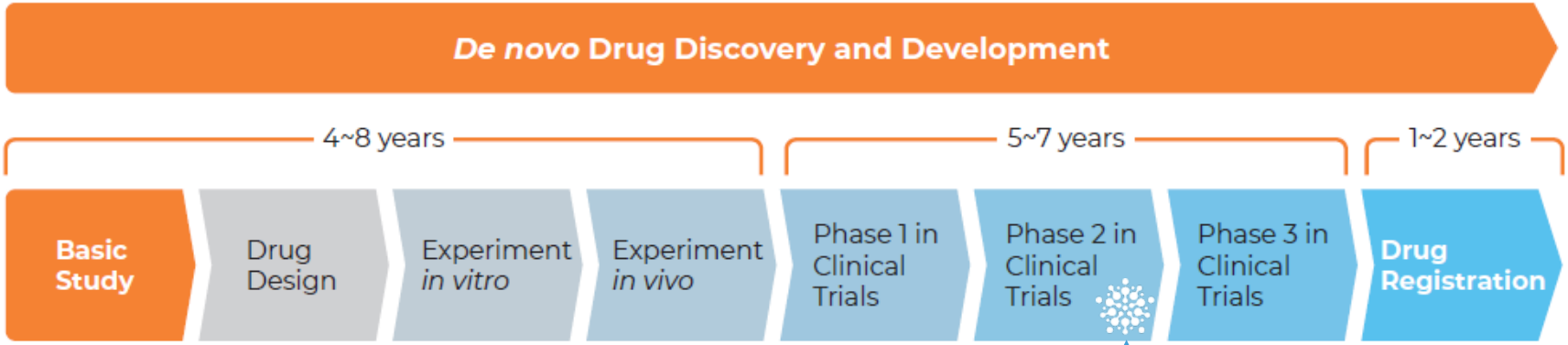
# COMPANY OVERVIEW



- Lead asset, ISLA-101 repurposed for dengue fever and other mosquito (or vector) borne diseases
- ISLA-101 has been part of 40+ Phase I, II and III human clinical trials in indications including cancer and respiratory diseases, and deemed safe by regulators
- Pre-clinical work at Monash University demonstrated promise as an antiviral drug
- ISLA-101 has US government and military support
- Phase 2a/b PROTECT trial has prophylactic (preventative) and therapeutic (treatment) arms via two patient cohorts
- Promising Phase 2a (preventative) cohort data allowed for start of Phase 2b (treatment) cohort
- Phase 2a/b high level results expected in May 2025
- IND (Investigational New Drug) status with the FDA provides Island with a streamlined pathway to market
- Effort to expand asset portfolio is well advanced

# 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

**Drug Repurposing**

**ILA is well advanced on its clinical development pipeline**

# INCREASED LIKELIHOOD OF SUCCESS



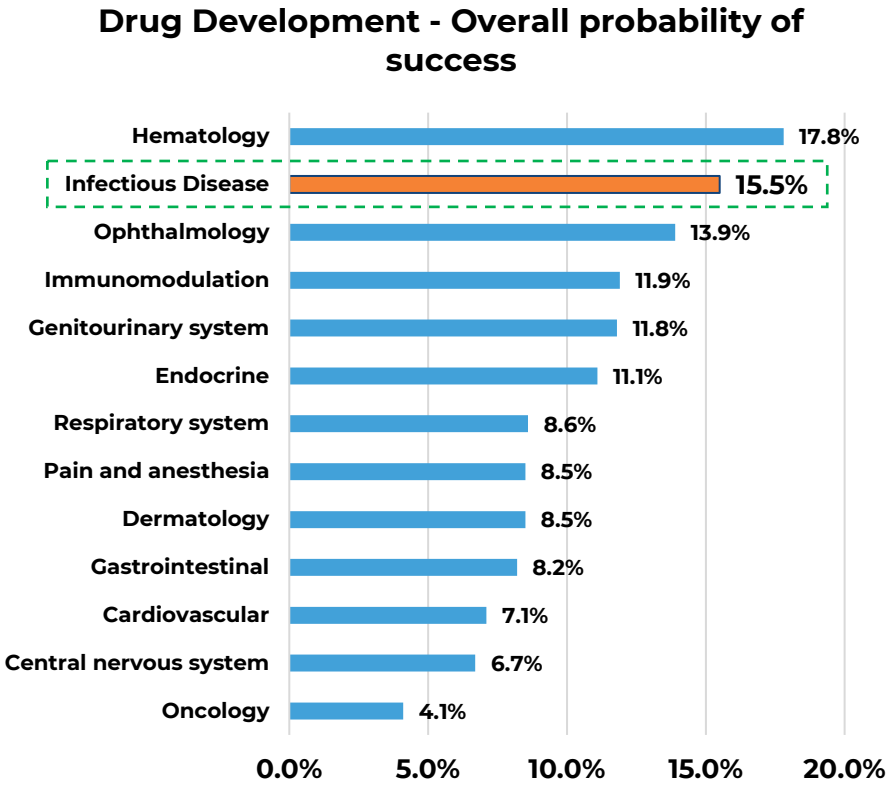
Treatments for infectious disease **have a statistically higher likelihood of overall success** in clinical trials

Anti-infective treatments sit at the low end of the drug development cost curve across all therapeutic areas

JAMA research shows that **anti-infective drugs were the least expensive to develop**[1]

Infectious disease treatments have the third-highest probability of phase II success (38.4%), behind hematology (48.1%) and metabolic (45%) treatments [2]

Probability of a successful phase III transition (post phase II) for infectious disease treatments increases to 64% [2]




[1] *JAMA Network: Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*

[2] *Biotechnology Innovation Organisation: Clinical development success rates and contributing factors 2011-2020*

# DENGUE – INFECTION CAN LEAD TO LETHAL OUTCOMES



Dengue is a viral infection transmitted to humans through the bite of infected mosquitoes

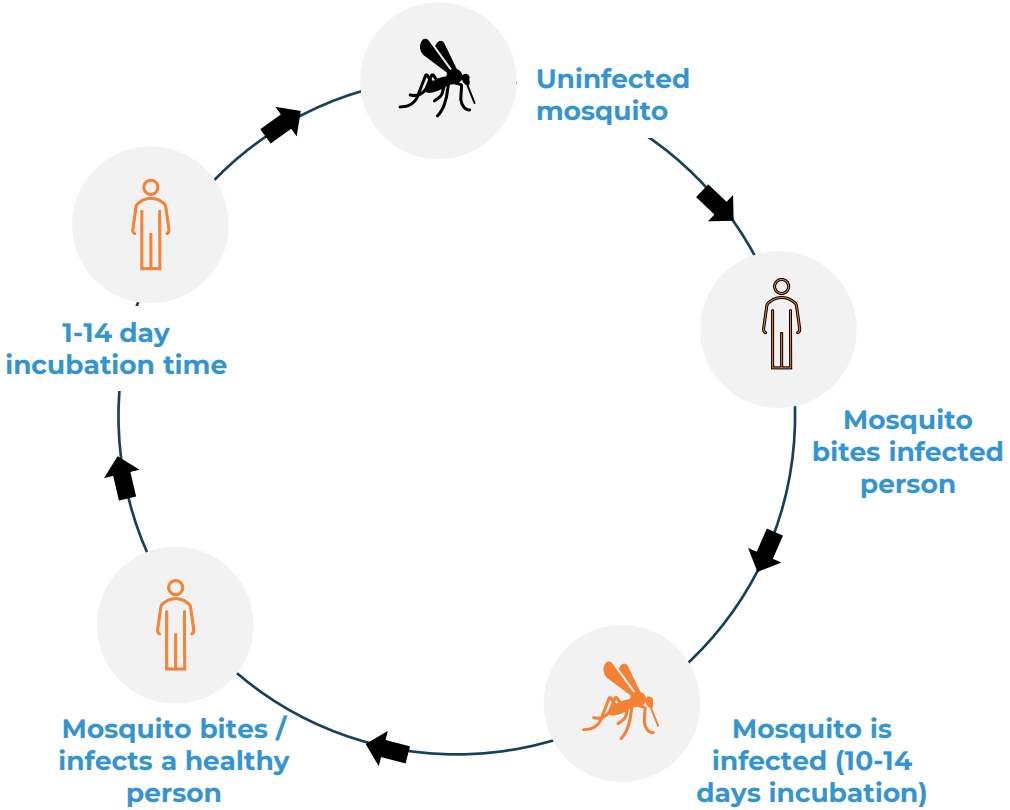
It directly impacts white blood cell count and platelets - vital for body protective mechanisms

Moderate to severe symptoms include high fever, muscle pain, shock, bleeding, vomiting and seizure amongst others

There is no specific treatment for dengue

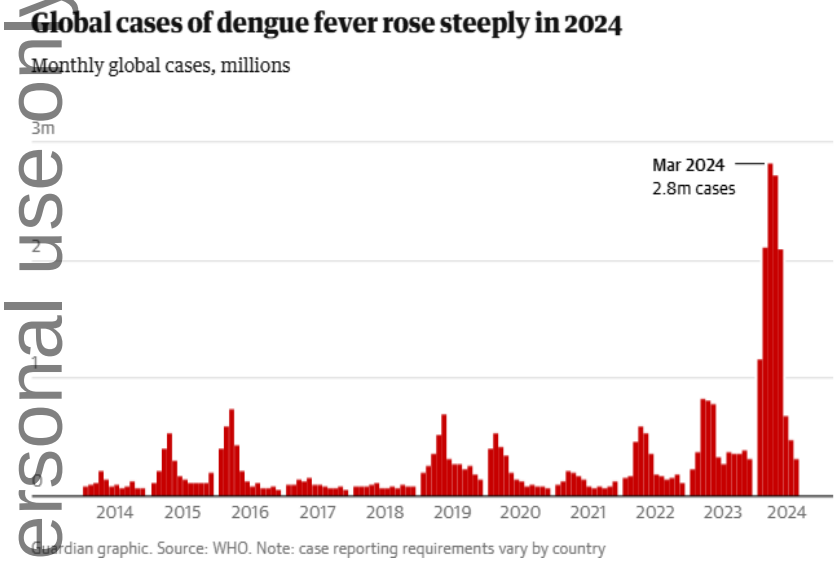
Some vaccines have been shown to have preventative nature but are in limited supply

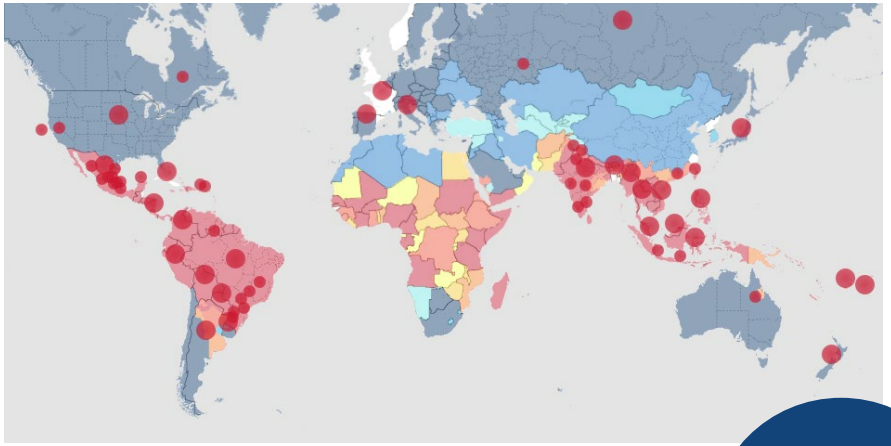
ISLA-101 is scalable oral dosing solution which has demonstrated activity against dengue strains



# DENGUE - COMMON AND SPREADING






*HealthMap: recent reports of local or imported dengue cases (March 2025)*

**US$8.9B**
Estimated impact to the economy from dengue fever

**"About half of the world's population is now at risk of dengue with an estimated 100 – 400 million infections occurring each year"**

*World Health Organisation, 30 May 2024*

# DENGUE BY 2050 IS MORE PREVALENT

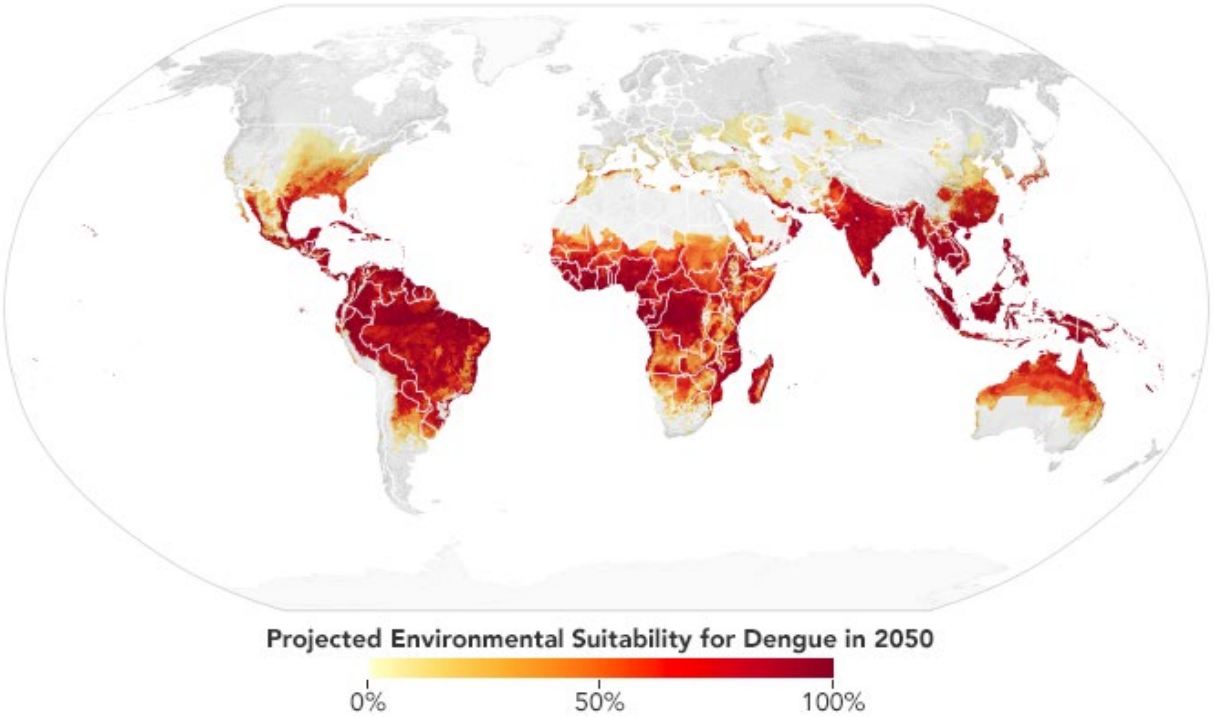


**Driven by:**

**Warmer temperatures**
- Accelerating development
- Increases activity of female mosquitoes
- Reduces incubation time for mosquito to become infectious
- Allow mosquitoes to survive longer through winter

**High humidity**
- Improves mosquitoes' chance of survival

**Extreme weather**
- Disrupts water / sanitation
- Increased flooding can enhance breeding




*NASA Earth Observatory map by Lauren Dauphin based on data from Janey Messina, University of Oxford - https://earthobservatory.nasa.gov/features/disease-vector*

# A MULTI-BILLION-DOLLAR MARKET OPPORTUNITY



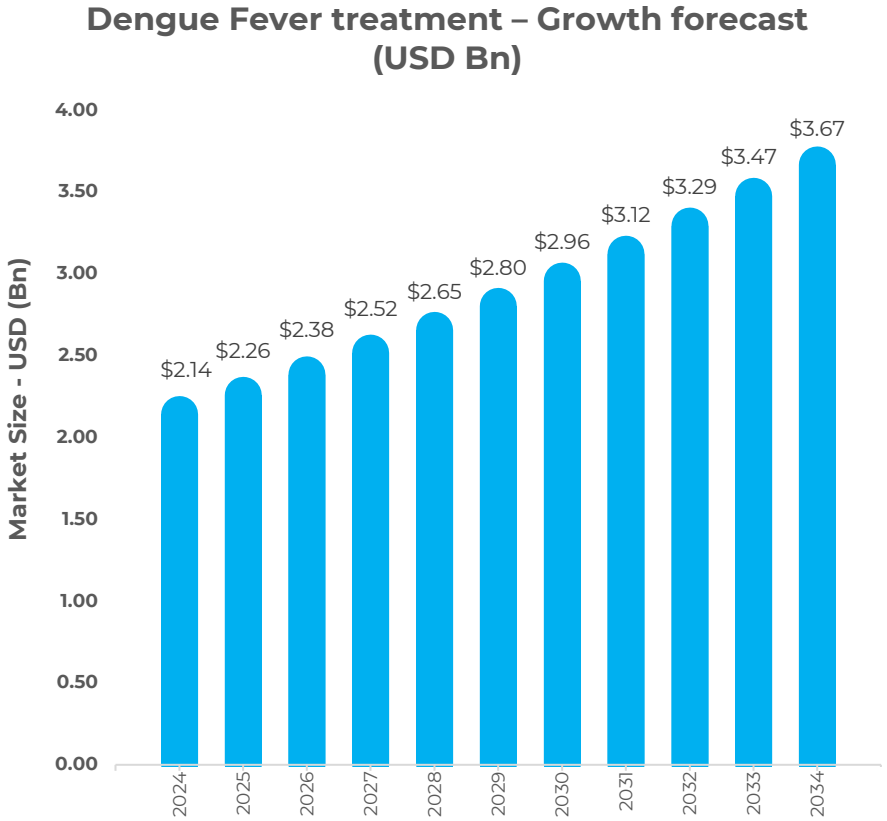
There is currently no specific treatment for dengue – providing ILA with the opportunity to be first to market

Takeda Pharmaceuticals project global sales (ex-USA) of its Qdenga dengue vaccine at US$1.6bn to US$2bn by 2030[1]

Qdenga is a prophylactic or preventative measure – ISLA-101 has the potential to become a treatment and/or prophylactic

Quick establishment of the antimalarial drug market highlights potential for dengue drug development trends

Antimalarial drug market was valued at US$1.76Bn in 2024 with a potential to grow to US$2.5Bn by 2030[2]




Source: Market Research Future (Rahul Gotadki, May 2025)

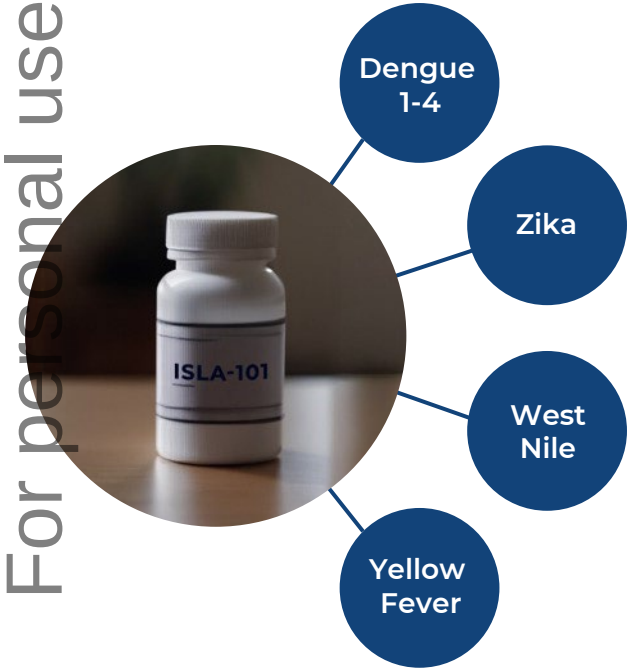
[1] *Antimalarial Drugs Market by Drug Class, Drug Type, Route of Administration, Malaria Type, Distribution Channel, End User - Global Forecast 2025-20*

[2] *Fierce Biotech: Takeda taps Biological E to ramp up Qdenga manufacturing capacity on quest to make 100M doses a year*

# ISLA-101 – BROAD ACTIVITY EVIDENT



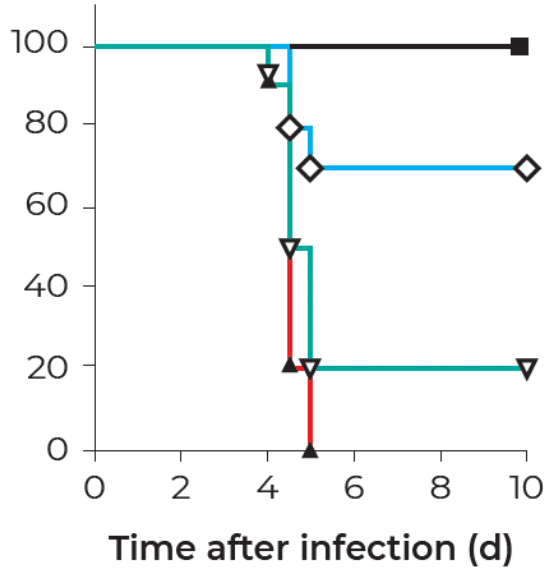
## Demonstrated activity against flaviviruses (subgroup of arboviruses) in models of infection




- ISLA-101 has demonstrated broad anti-viral activity in *in-vitro* models
- Demonstrated potent anti dengue-1 activity in *in-vitro* models using fresh human cells
- Protective in dengue fever and Zika in animal models
- Shown to prevent death in 70% of subjects in extremely lethal animal models
- Increasing concentrations of ISLA-101 prevent death induced by an otherwise lethal dengue fever infection
- 48 human clinical studies completed in other indications
- ILA's Single Ascending Dose study and further modelling reinforced safety / tolerability and identified dosing for Phase 2 trial

# PREVENTING ANIMAL DEATHS FROM LETHAL DENGUE AND PROTECTIVE AGAINST ZIKA






Two daily doses of Isla101 prevent 70% of deaths by otherwise lethal Dengue

Isla101 drug control
DENV
DENV+ Isla101 twice daily
DENV+ Isla101 once daily

Survival curve showing protection from lethal dengue change by Increasing dose of ISLA101 (mouse model).

*Fraser et al. J. Infect. Dis 2014*

# PHASE 2A/B (PROTECT) STUDY OVERVIEW



**Randomised, double blind, placebo-controlled dengue challenge study – prophylactic and treatment challenge:**

- Study include a prophylactic (Phase 2a) and therapeutic (Phase 2b) arm
- Prophylactic Cohort- 2a: 4 subjects randomized 3:1
- Therapeutic Cohort: 2b: 10 subjects randomized 8:2
- Primary endpoint:
  - Assess effect of ISLA-101 on viremia after challenge with DENV-1-LVHC
- Secondary endpoints:
  - Characterise clinical, immunologic and virologic responses following ISLA-101 after challenge with DENV-1-LVHC
  - Assess effect of ISLA-101 on clinical signs and symptoms after challenge with DENV-1-LVHC
  - Assess safety of ISLA-101 in the challenge with DENV-1-LVHC
- **High level, unblinded results from both cohorts expected this month**

Trial being conducted at SUNY Upstate Medical University Syracuse, New York.

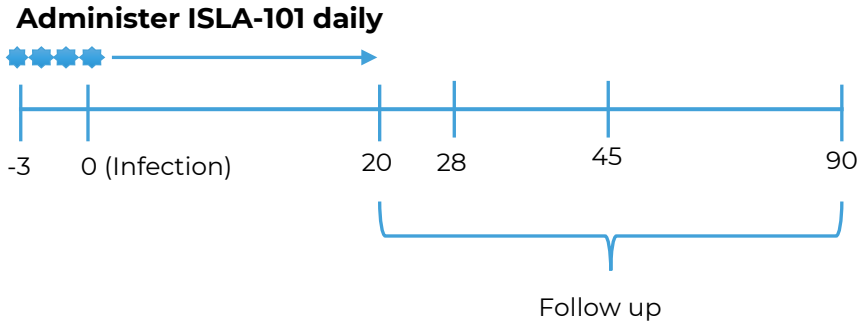
# PHASE 2A/B (PROTECT) DESIGN



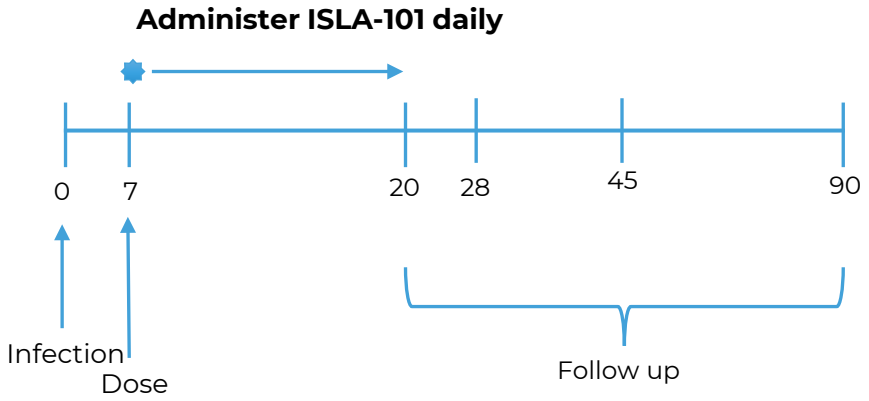
- Phase 1 (completed April 2024) achieved all study outcomes relating to safety and dosing, demonstrating benefit of Challenge study approach
- Phase 2a (prophylactic) subjects dosed in October 2024
- Safety Review Council review highlighted:
  - Administering ISLA-101 was safe
  - Study achieved appropriate ISLA-101 blood concentrations
  - Dosed subjects exhibited evidence of antiviral activity versus control
  - Unanimous decision to advance 2b cohort
- 2b (treatment) cohort administered ISLA-101 in February 2025
- Pharmacokinetic analysis of 2b cohort has shown target blood level concentration was achieved in all participants

**High-level, unblinded results this month**

**Phase 2A: Prophylactic (preventative) cohort**




**Phase 2B: Therapeutic (treatment) cohort**



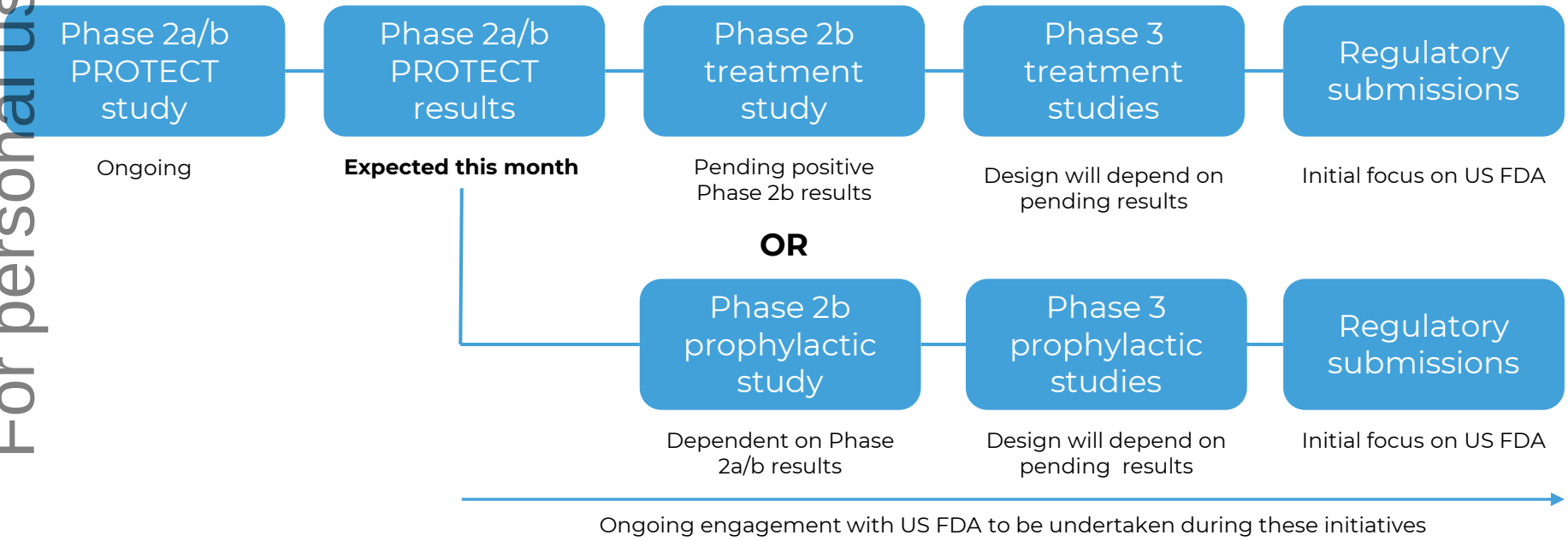
# CLINICAL TRIAL AND REGULATORY PATHWAY



## A defined clinical and regulatory route based on Phase 2a/b study results

Two likely pathways depending on Phase 2a/b results

Discussions advancing with multiple potential strategic partners for additional phase 2 and 3 clinical trials



# GALIDESIVIR WIP - SIGNIFICANT PIPELINE OPPORTUNITY

**Galidesivir – potential to tackle Ebola, Marburg, Zika & other RNA viruses**

- 12-month binding LOI signed in Sept 2024
- Small molecule, re-purposable with reduced timeframe to market
- Substantial Phase 1 human safety data
- Demonstrated efficacy in multiple lethal animal models – may provide access to FDA's Animal Rule
- Extensive US government funding to date
- PRV eligible across numerous potential indications
- Multiple commercial opportunities in travel, military, national safety and government stockpiling

# POTENTIAL REGULATORY FAST TRACK



## Existing Galidesivir data package and FDA Animal Rule unlock quicker approval path

Data package includes successful non-human primate study in Marburg and two phase 1 safety studies

FDA's Animal Rule allows for approval of drugs for in indications, based on animal efficacy data when human trials are unethical or infeasible, provided safety is shown in humans and the disease is well modelled in animals

ILA may have the potential to undertake one successful animal study, which would allow for submission of a New Drug Application (NDA) with the FDA – this approval would unlock a Priority Review Voucher, valued in excess of US$150m

PRV's are an incentive granted by the FDA allowing the holder to expedite the review of a future drug application, typically awarded for developing treatments for neglected tropical diseases or medical countermeasures

| Galidesivir transaction | ILA's maiden animal study | New Drug Application with FDA | Secure Priority Review Voucher | Drug development |
|---|---|---|---|---|
| Due diligence with BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) close to complete | Aim to complete within 12 months from completion of acquisition | Submission would be based on positive animal study results | Three most recent PRV's have been valued between US$103m – US$158m | Focus on potential for government stockpiling agreements |

# NEAR TERM MILESTONES



## A number of value catalysts pending in the coming months

| Milestone | Timeframe |
|---|---|
| Advancement of Galidesivir opportunity | May 2025 |
| High level, unblinded results from Phase 2a/b PROTECT study | May 2025 |
| Meeting with US FDA to discuss Phase 2a/b PROTECT study results | Q3 CY2025 |
| Completion of Phase 2/3 clinical trial pipeline planning | Q3 CY2025 |
| Commencement of Phase 2/3 clinical trials based on Phase 2a/b PROTECT study results | Q4 CY2025 |
| Ongoing engagement with potential partners for ISLA-101 clinical trial pathway | Ongoing |
| Assessment of additional pipeline opportunities to broaden asset portfolio | Ongoing |

Dates are indicative only, based on current estimates and subject to change

# Island Pharmaceuticals (ASX: ILA)


islandpharmaceuticals.com


@IslandPharma


Island Pharmaceuticals