
# COMBATTING URGENT VIRAL DISEASE THREATS

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(ASX: ILA)

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# Island Pharmaceuticals (ASX:ILA) is an antiviral therapeutics company targeting infectious diseases

## ASSETS:

- Known small molecules with clinical history
- Mid/late stage clinical or other abbreviated routes
- Open USFDA INDs
- Validated US Govt/military funding support
- Priority Review Voucher eligible

## RAPID PATHS TO MARKET

ISLAND PHARMACEUTICALS

Antiviral therapeutics

# ISLAND (ASX: ILA) AT A GLANCE

ISLAND PHARMACEUTICALS
Antiviral therapeutics

**Dengue infects up to 400m per year***

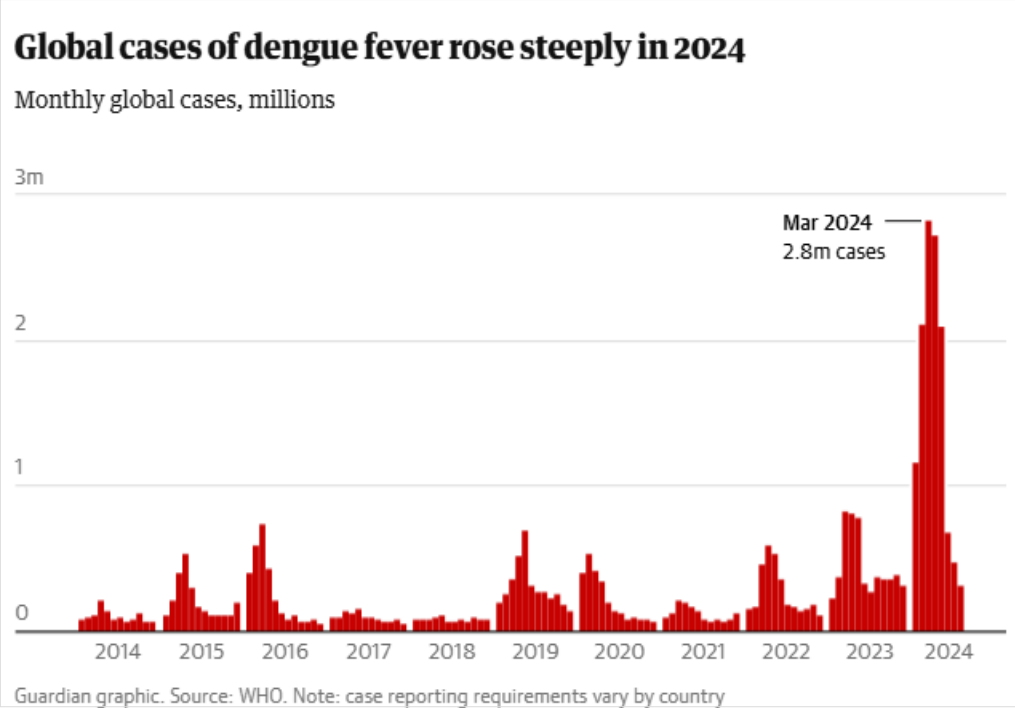
**Major market potential**

**Positive results in aggressive models**

**Phase 2a/b PROTECT clinical trial in dengue underway**

**Priority Review Voucher potential**

**Pipeline expansion in progress**



# ISLA-101 BROAD ACTIVITY EVIDENT

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


- In *in-vitro* models ISLA-101 has demonstrated broad anti-viral activity
- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated potent anti dengue-1 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
- *Island's own Single Ascending Dose study and further modelling reinforced safety / tolerability and identified Phase 2 dosing*

# PHASE 2a/b DENGUE (PROTECT) TRIAL STUDY

**"PROTECT"** study- A Phase 2a/b, Randomized, Double blind, Placebo-controlled Dengue Challenge Study – a PROphylactic and TrEatment Challenge Trial

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

**Phase 2a/b trial protocol: 2 cohorts**

1. Prophylactic Cohort- 2A: 4 subjects randomized 3:1
2. Therapeutic Cohort: 2B: 10 subjects randomized 8:2

**Primary endpoint**

- Assess the effect of ISLA 101 on 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 effect of ISLA 101 on clinical signs and symptoms after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

US$624k Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY to directly support PROTECT study.

# PHASE 2a/b CLINICAL TRIAL DESIGN

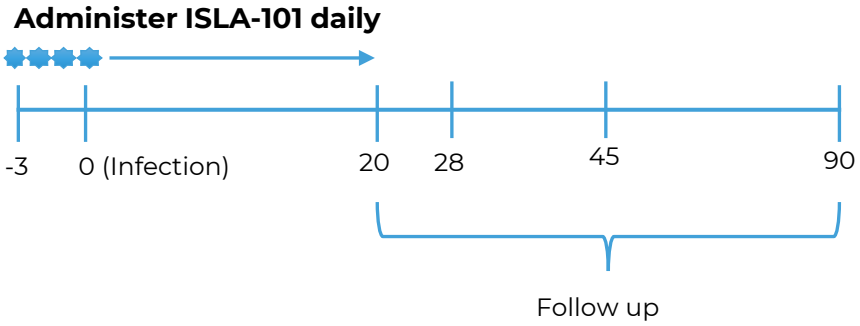
**Phase 2a/b trial protocol: 2 cohorts**

1. Prophylactic Cohort- 2a (left): 4 subjects randomized 3:1
2. Therapeutic Cohort: 2b (right): 10 subjects randomized 8:2

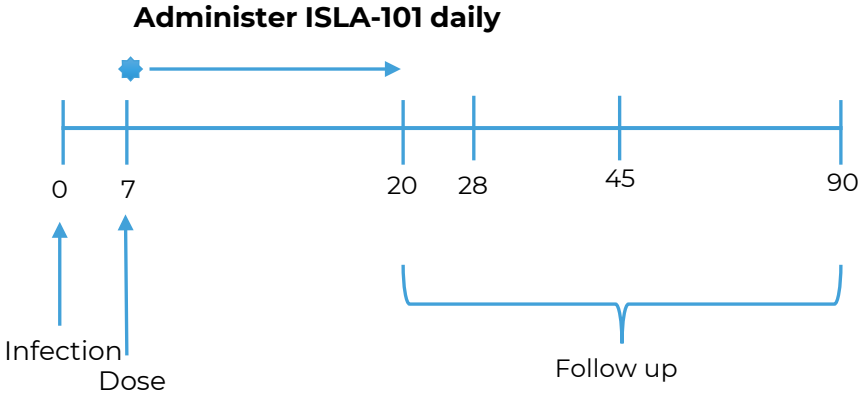
**Key near-term milestones:**

- Ethics approval received in August 2024, patient screening began in early September, with dosing expected to start imminently
- *Phase 2a read out expected by the end of 2024*
- *Phase 2b cohort dosing expected to commence in Jan 2025*

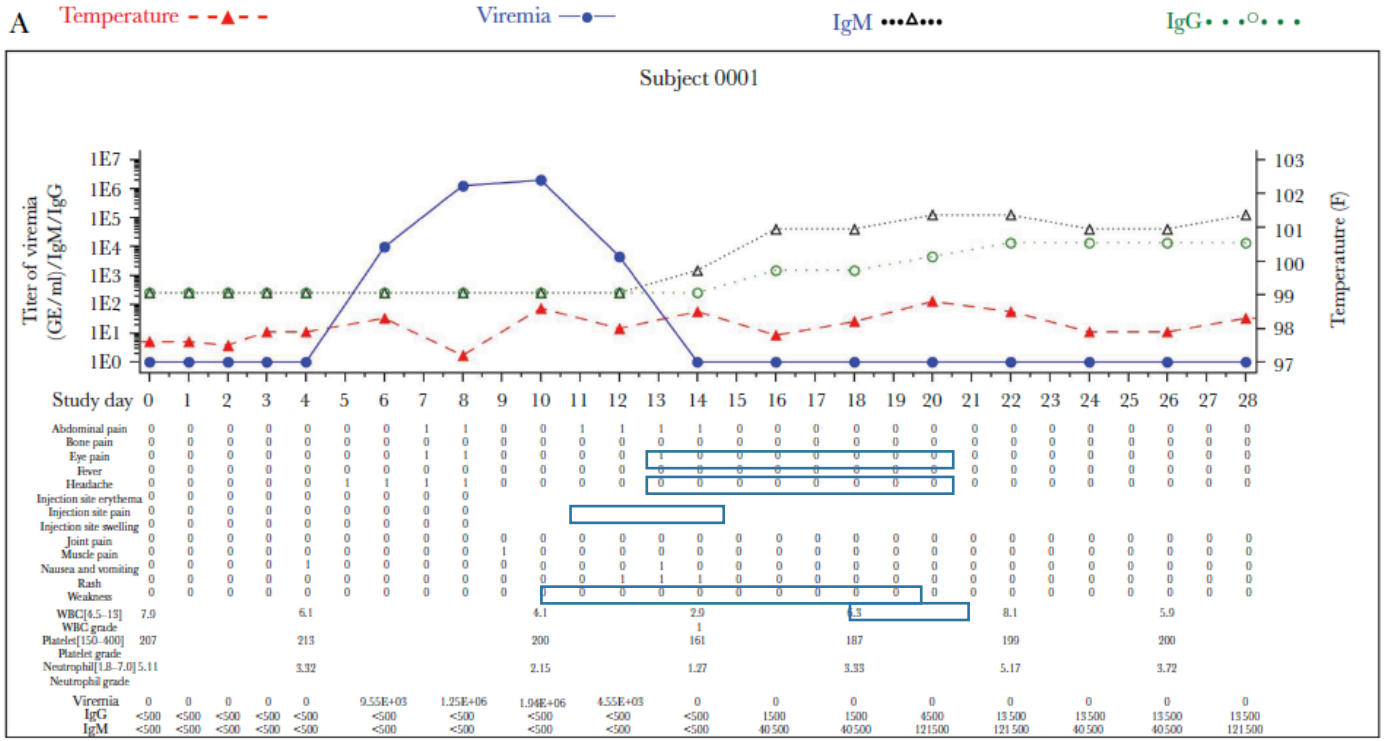
## Phase 2a: Prophylactic (preventative) cohort




## Phase 2b: Therapeutic (treatment) cohort



# PHASE 1 CONTROL DATA DEMONSTRATES BENEFIT OF CHALLENGE STUDY APPROACH




Endy et al, J Inf Dis 2021

Exemplary data from untreated subjects in a Phase 1 challenge trial.

# SAFETY REVIEW COMMITTEE RECOMMENDATION

- Safety Review Committee (SRC) has reviewed data from Phase 2a cohort
- Primary endpoint of Phase 2a cohort was reduction in viremia (virus level in blood)
- SRC conclusions:
  - ✓ Administering ISLA-101 was safe
  - ✓ Study achieved appropriate blood concentrations of ISLA-101
  - ✓ ISLA-101 dosed subjects exhibited reduced viremia compared to control
  - ✓ Unanimous decision to advance to Phase 2b cohort

# H1 MILESTONE ACHIEVEMENTS, H2 TARGET MILESTONES**

**H1 FY 2025 (Jul – Dec 2024)**

- Obtain ethics approval for Phase 2 trial
- Screening subjects in Phase 2a/b trial
- **Subjects dosed in Phase 2a trial arm**
- **Secures $3.5M in funding to support key inflection points**
- **Data readout from Phase 2a study**
- **Ongoing DD on Galidesivir program**
- **Ongoing discussions with potential partners**

**H2 FY 2025 (Jan – Jun 2025)**

- Subjects dosed in Phase 2b trial arm
- Data readout from Phase 2b study
- End of Phase 2a/b meeting anticipated with FDA
- Plans announced for next steps in clinical programs
- Ongoing discussions with potential partners

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