



SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA)
Online investor briefing

December 2022

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

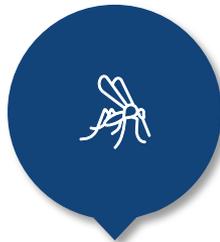


ISLAND AT A GLANCE



Advancing lead drug

ISLA-101 toward Phase 2
“PEACH”* clinical trial for the
prevention of dengue fever.



Dengue infects +390 million year

No current pharmaceutical treatment
for the disease. Limited access to only
one vaccine.



Major market potential

In mosquito-borne
diseases, exacerbated by
climate change.



Positive results in aggressive models

Of animal and human cellular models of
dengue fever and Zika infections + other
flavivirus data.



Priority Review Voucher potential

For ISLA-101 at the time of FDA approval.
Last ten PRVs sold for an average of
US~\$110M.



Pipeline expansion underway

Targeting other viruses with
significant unmet need and
limited competition.

**“DENGUE FEVER IS THE MOST RAPIDLY
SPREADING MOSQUITO-BORNE VIRUS
INFECTION IN THE WORLD.”**

World Health Organisation, 13 October 2022



ISLAND
PHARMACEUTICALS
Antiviral therapeutics

MOSQUITO BORNE VIRUSES: GLOBAL CHALLENGES



Miami under alert as first confirmed case of dengue fever is reported

By EL 2021 10:58 AM A.M. 10/20/21



View

<https://www.australiantgeographic.com.au/topics/wildlife/2021/11/upcoming-mosquito-season-may-be-the-worst-yet-heres-how-to-prepare-yourself/>
<https://www.abc.net.au/news/2022-03-23/australia-japanese-encephalitis-cases-in-ov/10036684>
<https://news.mongabay.com/2022/02/in-temperate-nepal-climate-change-paves-way-for-tropical-dengue-fever/>



Here's what we know about the Japanese encephalitis outbreak in Victoria, South Australia, NSW and Queensland

By Freya Michie and Siân Johnson

Posted Wed 9 Mar 2022 at 1:52pm, updated Wed 9 Mar 2022 at 5:41pm



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



HEADLINES

Dengue cases continue to rise – DOH

Rhodia Villanueva - The Philippine Star

August 3, 2022 | 12:00am



<https://www.straitstimes.com/singapore/health/more-than-30000-dengue-cases-reported-in-2022-6-times-that-of-2021-nea>
<https://www.pbs.org/newshour/health/altering-climate-change-the-u-s-could-become-ideal-for-west-nile-to-thrive>
https://www.islandpharm.com/news/miami-under-alert-as-first-confirmed-case-of-dengue-fever-is-reported/article_4760e99e-074f-11ed-a34a-833a66847777.html
<https://www.philstar.com/headlines/2022/08/03/2199848/dengue-cases-continue-rise-doh>

THE STRAITSTIMES

More than 30,000 dengue cases reported in 2022, six times that of 2021: NEA



The NEA has attributed the high number of cases this year to the DENV-3 strain of dengue. PHOTO: ST FILE



In temperate Nepal, climate change paves way for tropical dengue fever

by Akhaya Raj Joshi on 31 October 2022



IND SUBMISSION IMMINENT

IND IS THE LAST STEP, ENABLING PEACH STUDY COMMENCEMENT

Sponsor information (complete)

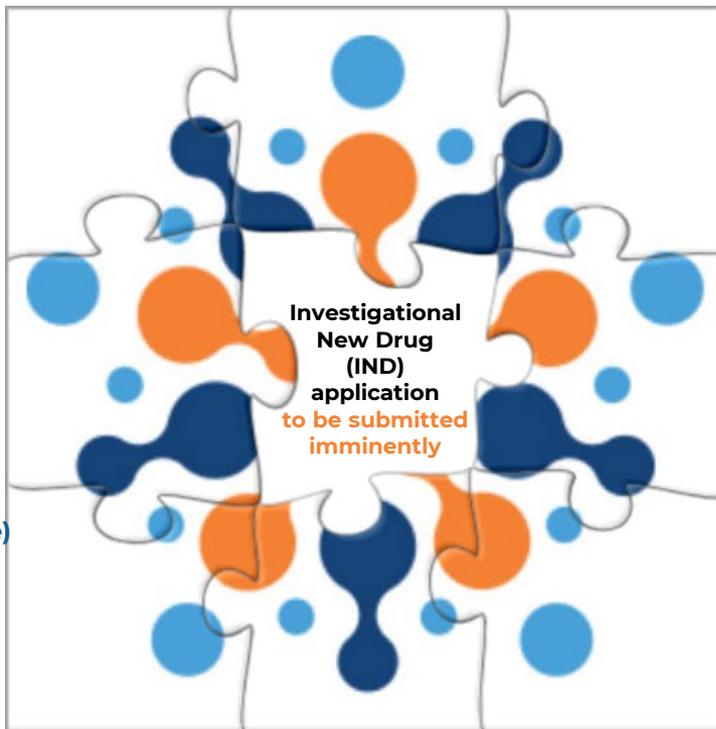
Summary of existing human data (complete)

- ✓ ~45 previous clinical trials
- ✓ Human safety data

Trial monitoring and biostatistics plan (complete)

Preclinical work (complete)

- ✓ Animal pharmacology
- ✓ Toxicology
- ✓ pharmacokinetic data



Clinical trial protocol (Complete)

Drug manufacturing (complete)

- ✓ Drug substance (API)
- ✓ Drug product

Investigator's brochure (complete)

- ✓ A major body of work – includes all instructions to enable the principal investigator to run the trial

Chemistry, manufacturing and control information (complete)

- ✓ Manufacturing method
- ✓ Manufacturing validation
- ✓ Drug substance manufacturing data for clinical batch
- ✓ Final clinical drug product for ISLA-101 trial manufactured

MANUFACTURING NOW COMPLETE



Manufactured capsules
being processed



Stability now achieved
on packaged drug
product

PHASE II DENGUE (PEACH) TRIAL STUDY IN DETAIL

"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 18-55
- Willing to use contraception for the duration of the study
- Informed consent

Exclusion

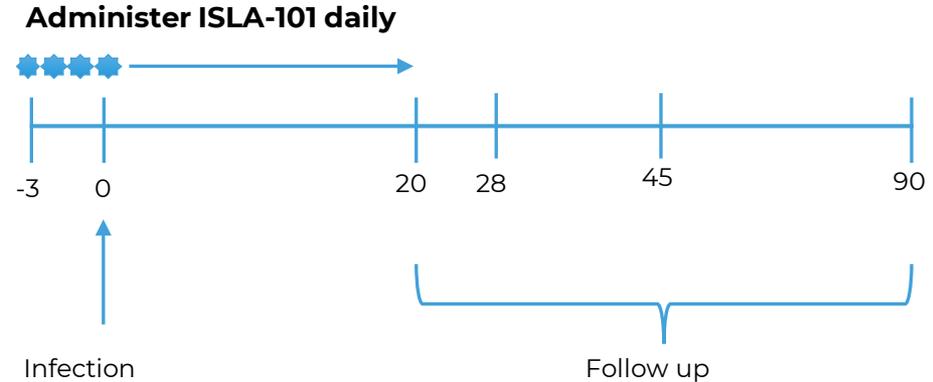
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

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

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.



Kevin Swiss, CMC Consultant

Regulatory CMC expert,
experienced in pharma from
IND to post-approval,
successfully led foreign
companies through FDA PAIs.

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.

UPCOMING MILESTONES

H1 FY 2022

(July-Dec 2021)

- ✓ Sign SUNY CTA
- ✓ Announce Principal Investigator
- ✓ Engaged CRO
- ✓ Drug substance (API) manufactured
- ✓ Advance research collaboration

H2 FY 2022

(Jan-June 2022)

- ✓ New drug product manufacturer secured
- ✓ Analytical method development
- ✓ Advancing IND

H1 FY 2023

(July-Dec 2022)

- ✓ Clinical material manufactured
- ✓ Clinical material released and shipped to site
- Finalize and File IND
- ✓ Institutional Review Board application filed

H2 FY 2023

(Jan-June 2023)

- Open IND
- Screening, enrolment, dosing subjects in PEACH* trial
- Advance through PEACH cohorts
- Trial read out
- 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

PHARMACEUTICALS

Antiviral therapeutics

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