SOLVING URGENT VIRAL DISEASE THREATS

(ASX: ILA) | November 2023

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

ISLAND AT A GLANCE

Dengue infects up to 400m per year*

Now **endemic in more than 100 countries** with no current pharmaceutical treatment.

Major market potential

ISLA-101 has potential to address mosquito-borne diseases, which are being driven by **climate change.**

Positive results in aggressive models

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

Advancing Single Ascending Dose study

Measure of **blood concentration of ISLA-101**, following administration-increasing doses of ISLA-101.

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.**

**WHO, 17 March 2023.*

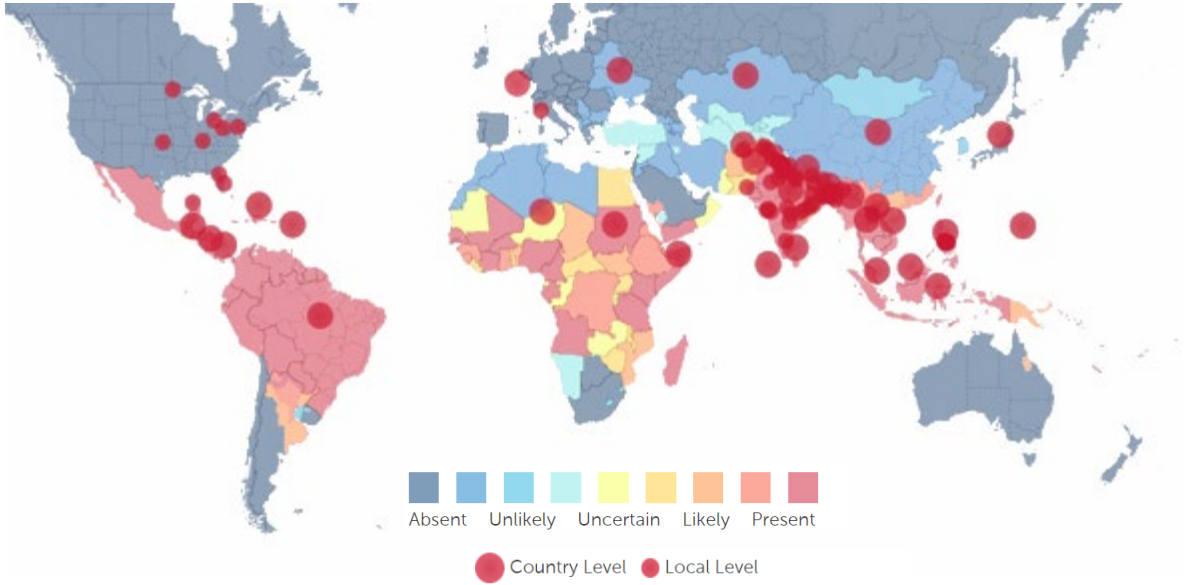
“About half of the world's population is now at risk of dengue with an estimated 100–400 million infections occurring each year”

World Health Organisation, 17 March 2023

DENGUE IS A WIDESPREAD ISSUE

Dengue outbreaks occurred in many countries of the world in the Americas, Africa, the Middle East, Asia, and the Pacific Islands

HealthMap: recent reports of local or imported dengue cases



Sri Lankan authorities rush to contain dengue fever outbreak

Vietnam's dengue fever cases nearly top 100,000

Bangladesh reports 509 dengue hospitalisations, two deaths in a day

Singapore on alert for fresh dengue fever outbreak

Malaysia dengue cases top 54K, Up 150% from last year - Outbreak News Today

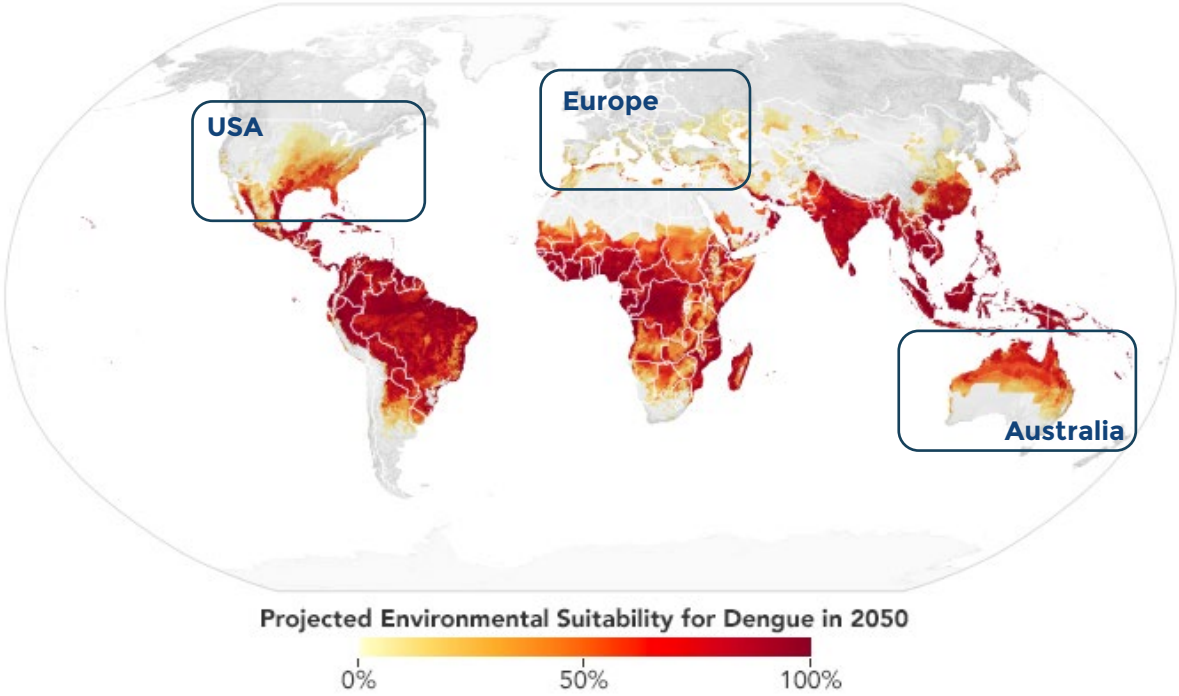
Peru declares national emergency as dengue outbreak kills 200 and swamps hospitals

Dengue cases reach 647 in Barbados

https://www.healthmap.org/dengue/en - visited September 4, 2023

DENGUE IN 2050 – A GLOBAL DISEASE

Prediction based on projections of future temperatures, rainfall, and mosquito populations



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


“Dengue fever will become a major threat in the southern US, southern Europe and new parts of Africa this decade”
World Health Organisation, 6 October 2023

COMMERCIAL OPPORTUNITY

ISLA-101 has potential as both a prophylactic and therapeutic

Travelers

The malaria market, expected to reach US$1B by 2026[1], is expanding to an increasing number of countries

Military

Partnering with army (CRADA in place) for Phase 2a clinical trial in Dengue Fever, to be pursued as Isla-101 is closer to approval

National Outbreaks

Millions of patients in Latin America offer potential for sales in disease suppression and treatment during outbreaks

Government Stockpiles

Potential for endemic countries to establish and maintain drug stockpiles as happens with influenza

Priority Review Voucher

Last ten PRVs sold for an average of US~$110M, with potential for ISLA-101 at the time of FDA approval

1. *https://www.alliedmarketresearch.com/anti-malarial-drug-market*

Introducing ISLA-101

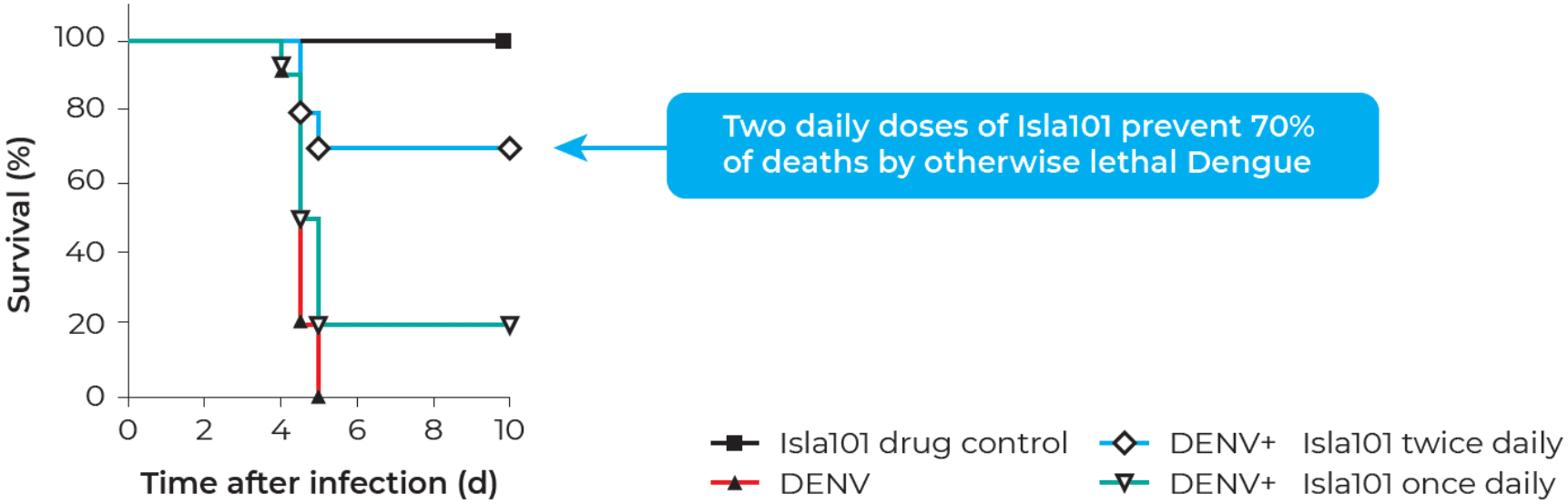
ISLA-101 BROAD ACTIVITY EVIDENT

Demonstrated activity against flaviviruses (a subgroup of arboviruses) 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
- 45 HUMAN Clinical Studies of ISLA-101 completed in other indications

PREVENTS ANIMAL DEATHS FROM LETHAL DENGUE

ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.



Survival curve showing protection from lethal dengue change by Increasing dose of ISLA101 (mouse model).
Fraser et al. J. Infect. Dis 2014

RECENT ISLA-101 PROGRESS

ILA submits IND to US FDA for Phase 2a PEACH clinical trial

Dec 2022

ILA receives FDA feedback on Phase 2a clinical study; clinical hold

Jan/Feb 2023

ILA submits responses to FDA questions for ISLA-101

Apr 2023

ILA receives FDA go-ahead for ISLA-101 program; clinical hold lifted

May 2023

Grant research support announced for the planned PEACH study in dengue fever

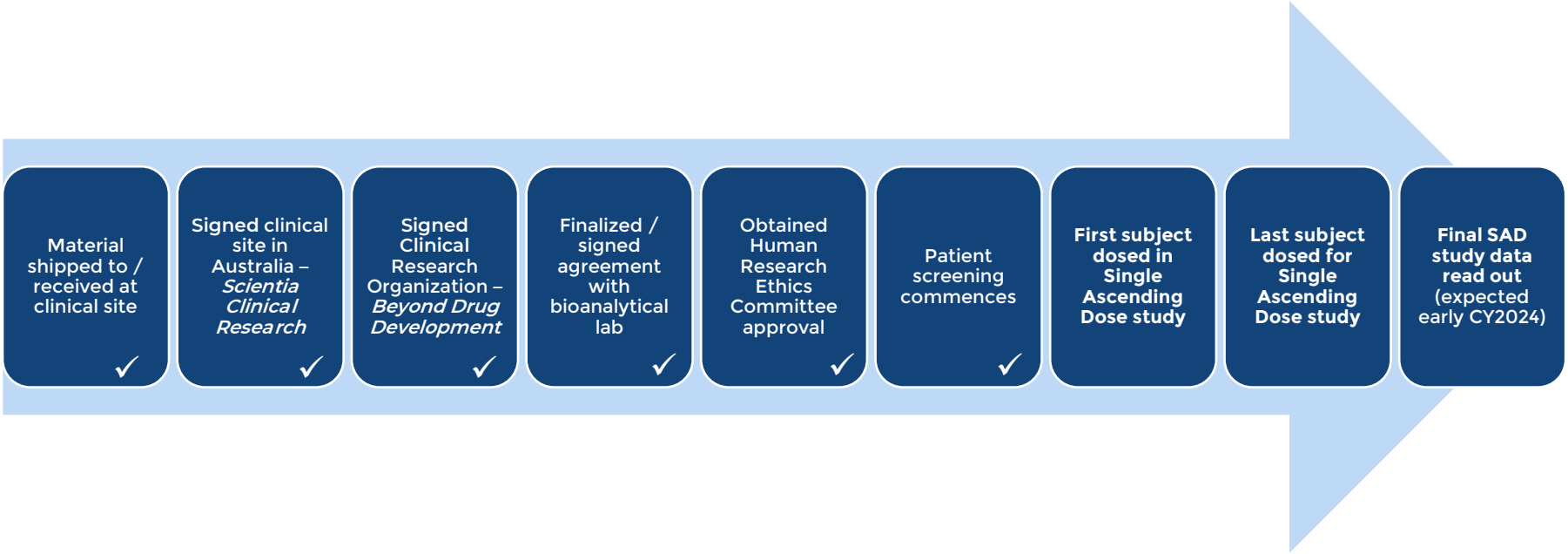
Jul 2023

Received human research ethics committee approval to commence Single Ascending Dose study

Nov 2023

SINGLE ASCENDING DOSE STUDY – KEY ACTIVITIES

Several workstreams are underway, providing support for commencing the Single Ascending Dose study



SINGLE ASCENDING DOSE STUDY PROTOCOL

The aim of the study is to ensure that administered doses which increase over time could safely achieve blood concentrations of ISLA-101 that are predicated to be effective against the dengue virus.

Inclusion

- 4 cohorts of 8 healthy subjects
- Age 18-65
- 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

Dosing

- Doses are 300, 600, and 900 mg/m^2, under fasted conditions. The 900 mg/m^2 (or highest safe dose) cohort will repeat the dosing under fed conditions.
- 5 day stay in the clinical research unit followed by a final safety follow-up visit at Day 8.
- After each cohort, a Safety Review Committee will review safety data and determine if it is safe to move to the higher dose.

The study is expected to be short with dosing expected to commence in late 2023 and read out in early 2024. It will be run in Australia, enabling access to the Australian Federal Government's R&D tax incentive.

STUDY PARTNERS

Scientia Clinical Research is an FDA audited, early phase clinical trials facility, with world-class clinical trial expertise and state of the art facilities.

Scientia is the clinical site for the ISLA-101 Single Ascending Dose, dose escalation study.

Beyond is a leading Contract Research Organisation (CRO) based in Brisbane, Australia, with a focus on product development and early phase research.

Beyond brings extensive industry experience, through its expert team (averaging 20 years' experience) and strong reputation in serving early to mid-stage biotech companies and established pharmaceutical companies.

ISLA-101 DEVELOPMENT MILESTONES

- Island expects to have final data from the Single Ascending Dose study for ISLA-101 in early CY2024
- The company plans to seek a meeting with the US FDA to discuss the study outcomes and strategies for how to maximise the data obtained from the PEACH* study
- The PEACH study protocol may then be amended based on FDA feedback
- Island has agreements and study partners in place for the PEACH study, so would expect to commence the study quickly once FDA feedback has been incorporated into the protocol

* The “PEACH” study – a Phase 2a, Randomized, Double blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model, will be run at SUNY Upstate Medical University Syracuse, New York

PHASE II DENGUE (PEACH) TRIAL STUDY

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

Exclusion

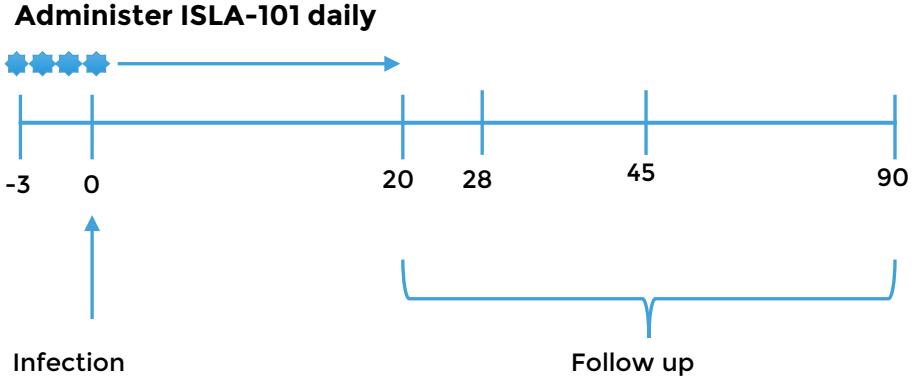
- Female: pregnant or lactating
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

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

- 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



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

US$1.3m Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY will support laboratory testing and data analysis during Island's PEACH study.

BUILDING OUR PIPELINE

- In addition to ISLA-101, Island is exploring the acquisition or in-licensing of new drug candidates
- Specific screening and scoring criteria being applied, based in part on the following criteria:
  - small molecule program
  - anti-viral
  - eligible for a Priority Review Voucher
  - possible non-dilutive funding to support clinical studies.

BOARD AND CORPORATE SNAPSHOT

Dr Paul MacLeman
Executive Chairman

Dr Paul MacLeman brings decades of experience across the life sciences sector, including veterinary practice, pharmaceutical development and manufacturing, biotechnology, diagnostics and finance.

Dr David Foster
Managing Director

Dr Foster has 25+ years experience in life sciences representing pharmaceutical, biotherapeutic and diagnostic companies, while in private legal practice.
He has co-founded a number of biotechnology companies as well as BioNTX, a regional life science trade association.

Dr David Brookes
Non-Executive Director

Dr David Brookes has extensive experience in the health and biotechnology industries, first becoming involved in the biotechnology sector in the late 1990's as a consultant. Dr. Brookes has since held Board positions in a number of ASX listed biotechnology companies, including as Chairman of genomics solutions company, RHS Ltd.

Mr Albert Hansen
Non-Executive Director

Mr Al Hansen is the Managing Partner. KESA Partners. He brings 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.

Dr Anna Lavelle
Non-Executive Director

Dr Lavelle is 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.

ISLAND PHARMACEUTICALS
Antiviral therapeutics

Corporate snapshot
Key data points

$0.076 Share Price (AUD) (As at 9 Nov 2023)	**$6.18m** Market Cap (As at 9 Nov 2023)
80,968,468 Ordinary shares on issue (As at 9 Nov 2023)	**A$1.41m** Cash (As at 30 Sept 2023)

OTHER KEY TEAM MEMBERS

Bobbi Drais
Senior Regulatory Consultant

Bobbi is a dynamic global leader with an impressive track record spanning over 25 years in regulatory affairs, specialising in regulatory strategic management in biologics, Advanced Therapy Medicinal Products, Prescription and OTC Drugs, Medical Devices and Cosmetics. She was also a former senior executive serving as member of multiple executive leadership teams with extensive experience in designing, developing and leading global regulatory teams.

She has proven success in the development of regulatory strategy to support optimal progress of projects from product development through to initial approval as well as geographical roll-out and post-market compliance activities.

Teresa Byrne
Vice President Clinical Product Development

Teresa is an experienced Clinical Research Executive, with more than 20 years of pharmaceutical industry experience from the research bench to the clinic. She has experience in both large pharmaceutical companies as well as in smaller biotech companies and CRO organisations.

Teresa has held clinical operations leadership roles at Janssen Research & Development (a Johnson & Johnson company), Novartis Vaccines, and GlaxoSmithKline. In addition, Teresa served as the Director of Clinical Quality Assurance for BioMotiv, a biotech accelerator. Most recently, she led Clinical Development for Cersci Therapeutics, a small biotech company acquired by Acadia Pharmaceuticals.

SCIENTIFIC ADVISORY SLIDE

Dr Leigh Farrell

Leigh has over 30 years' experience in the biotechnology and pharmaceutical industry and is Head of Health Security Systems Australia, a Division of DMTC Ltd, is a non-executive director of Pro Medicus Ltd, Ena Respiratory Pty Ltd and Axelia Oncology ty Ltd, and is a member of the Walter and Eliza Hall Institute of Medical Research Board Commercialisation Committee and a member of the Independent Advisory Council of Medicines Australia.

Leigh's past appointments include: Senior Vice President, Commercial at Certara USA, Inc where he was responsible for Asia Pacific Commercial and global government engagement for the preparedness, planning and response to major health emergencies; Chairman & COO of d3 Medicine, LLC; Vice President of Business Development at Biota Pharmaceuticals Ltd, Research Manager Johnson & Johnson Research and CEO of Gene Shears Pty Ltd. Leigh holds a PhD in Biochemistry and a Bachelor of Science (Honours) from Monash University and is a Fellow of the Australian Institute of Company Directors.

Prof Stephen Thomas MD

Professor Stephen Thomas, MD has an 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.)

He had twenty years in the U.S. Army Medical Corps serving at the Walter Reed Army Institute of Research (WRAIR.)

Dr Amy Patick

Amy Patick is a scientific consultant with deep expertise in antiviral drug discovery, development and viral resistance with broad know how in emerging virus epidemics and translational medicine.

Previously, Dr. Patick has served as Vice President, Research at Adamas Pharmaceuticals, Vice President, Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, Inc. and Research Scientist at Bristol-Myers Squibb Company. Dr. Patick has also served as President for the International Society of Antiviral Research.

Dr. Patick was a postdoctoral fellow in immunology at the Mayo Clinic/Foundation in Rochester, MN and received her PhD in Medical Microbiology from the University of Wisconsin, Madison.

UPCOMING MILESTONES

Completed

- Investigational New Drug application for ISLA-101 PEACH study opens
- Foundational work in progress for SAD study (site selection, CRO selection, etc)
- Finalize agreements for clinical site and CRO

H1 FY 2024 (Jul – Dec 2023)

- Key US and Australian patents granted for ISLA-101
- Obtain HREC (i.e. IRB) approval
- Screen, enrol and dose volunteers in SAD study
- Successful progression through cohorts

H2 FY 2024 (Jan – Jun 2024)

- Dose final Single Ascending Dose study subject
- Single Ascending Dose study read out
- Seek FDA meeting on PEACH study protocol
- Pipeline expansion efforts
- Initiate PEACH trial

** PEACH: Phase 2a, randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model.*

Contact

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