



**10 July 2024**

ASX Announcement

**Island Pharmaceuticals presentation for  
Bioshares 2024 Conference**

**MELBOURNE Australia, 10 July 2024:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to provide a copy of the presentation that will be delivered at the Bioshares 2024 conference this week.

**Bioshares conference information**

Dr MacLeman is presenting as part of Session 4: Repurposing Existing Pharmaceuticals, from 5.10pm - 5.30pm this coming Friday July 12 2024.

More information on the Bioshares conference is available here:  
<https://www.bioshares.com.au/summit/18th-bioshares-biotech-summit-1?EventGuid=8d415f38-3333-4b9d-ae86-89de1692ba5d>

Any investors interested in meeting with Island at Bioshares are invited to contact us using the details below.

**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:**

Dr Paul MacLeman  
Executive Chairman  
Island Pharmaceuticals Ltd  
[info@islandpharmaceuticals.com](mailto:info@islandpharmaceuticals.com)

Investors and media, for further information, please contact:

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IR Department  
Mobile: +61 411 117 774  
[jane.lowe@irdepartment.com.au](mailto:jane.lowe@irdepartment.com.au)



## About Island Pharmaceuticals

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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 dengue<sup>2</sup> 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 the Company's share registry, Automic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.*

Visit [www.islandpharmaceuticals.com](http://www.islandpharmaceuticals.com) for more on Island.



# ADDRESSING URGENT VIRAL DISEASE AND MEDICAL COUNTERMEASURES THREATS

DR PAUL MACLEMAN,  
EXECUTIVE CHAIR

BIOSHARES CONFERENCE | JULY 2024

(ASX: ILA)

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## **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.

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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.



# ADDRESSING URGENT VIRAL DISEASE AND AND MEDICAL COUNTERMEASURES THREATS

## 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

# STRATEGIC CHECKLIST



- Clinical history
- Small molecule
- Proven preclinical anti-viral activity
- Eligible for Priority Review Vouchers
- National and military preparedness need
- Probable/confirmed non-dilutive funding to support: military, civilian, NGO
- Fit for our management and advisory team: mid/late stage drug development, extensive medical countermeasures experience and roles





# STRATEGIC CONNECTIVITY BETWEEN ASSETS ISLA101 (FENRETINIDE) AND GALIDESIVIR

Both assets are:

- Phase II or later
- Have open Investigational New Drug applications with FDA
- Antivirals, therefore fast to develop and potential for early licensing if sought
- Supported by governments and military; needed for outbreaks and medical countermeasures
- Priority Review Voucher eligible (multiple options)
- Capable of multiple ‘shots on goal’: each has many potential disease targets



# About ISLA-101





**“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*

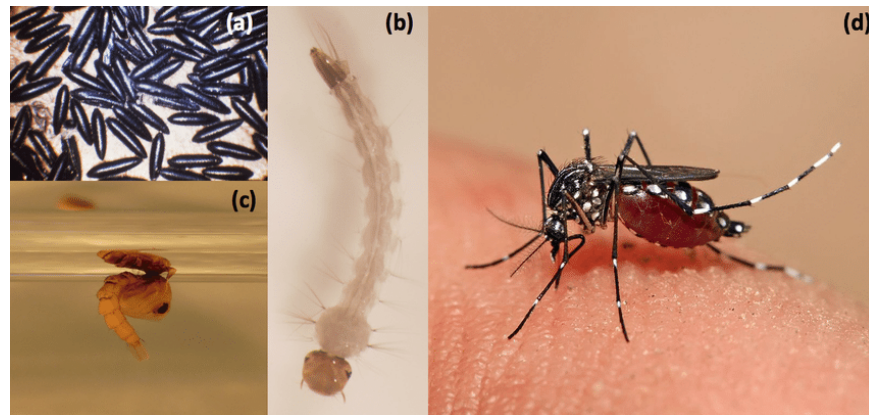


# TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET



## ISLA-101 – dengue, Zika, Yellow Fever, Chikungunya, other arboviruses

- 45+ human trials of ISLA-101 completed in other indications
- Island's recent SAD study reinforced safety and established the effective human EC50 dose
- Infectious disease, so trial endpoints are rapidly achieved
- Multiple PRV options
- CRADA with US military
- Entering Phase II now (Jul24)



Single Ascending Dose study showed 2-3x bioavailability in fed subjects

Now exploring combined prophylactic / therapeutic Phase II study with FDA.

# DENGUE IS CLOSE TO HOME



10 ° 7' 24 "



news.com.au

Sign

National World Lifestyle Travel Entertainment Technology Finance Sport Shopping

Travel Updates > Travel Stories

## Deadly viral infection doubles in popular tourists spots for Aussies

Known as the 'bone crushing fever', it made one Aussie model feel like she'd been "hit by a bus". Now, the virus is occurring in numbers never seen before.



Vanessa Brown

@vanessaibrown 4 min read May 26, 2024 - 8:02AM news.com.au

Source 1

yahoo!news

News Latest National World Environment

## Bali tourists urged to follow simple measures after tropical disease cases 'double'

Not only is the virus causing people to fall extremely ill, in some instances, travel insurance costs can soar into the tens of thousands.



Brianne Tolj · Associate News Editor

Updated 21 May 2024 · 4-min read

Source 2

NBC NEWS

Dengue fever, once confined to the tropics, now threatens the U.S.

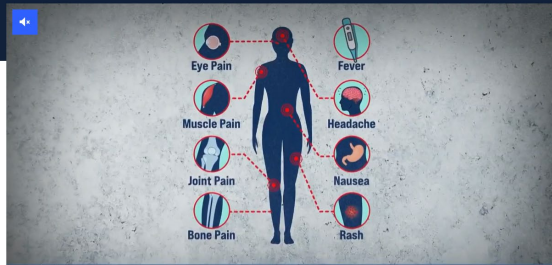
SHARE & SAVE - f X Email ...

HEALTH NEWS

## Dengue fever, once confined to the tropics, now threatens the U.S.

Climate change is expanding the habitat of the mosquitoes that carry the disease, allowing them to spread further north.

Source 3



euronews.health

HEALTH HEALTHCARE NUTRITION WELLBEING SERIES

Home > Health > Health news

## France warns of surge in imported dengue cases ahead of Olympics

(Described as potential super-spreader event)

Source 4

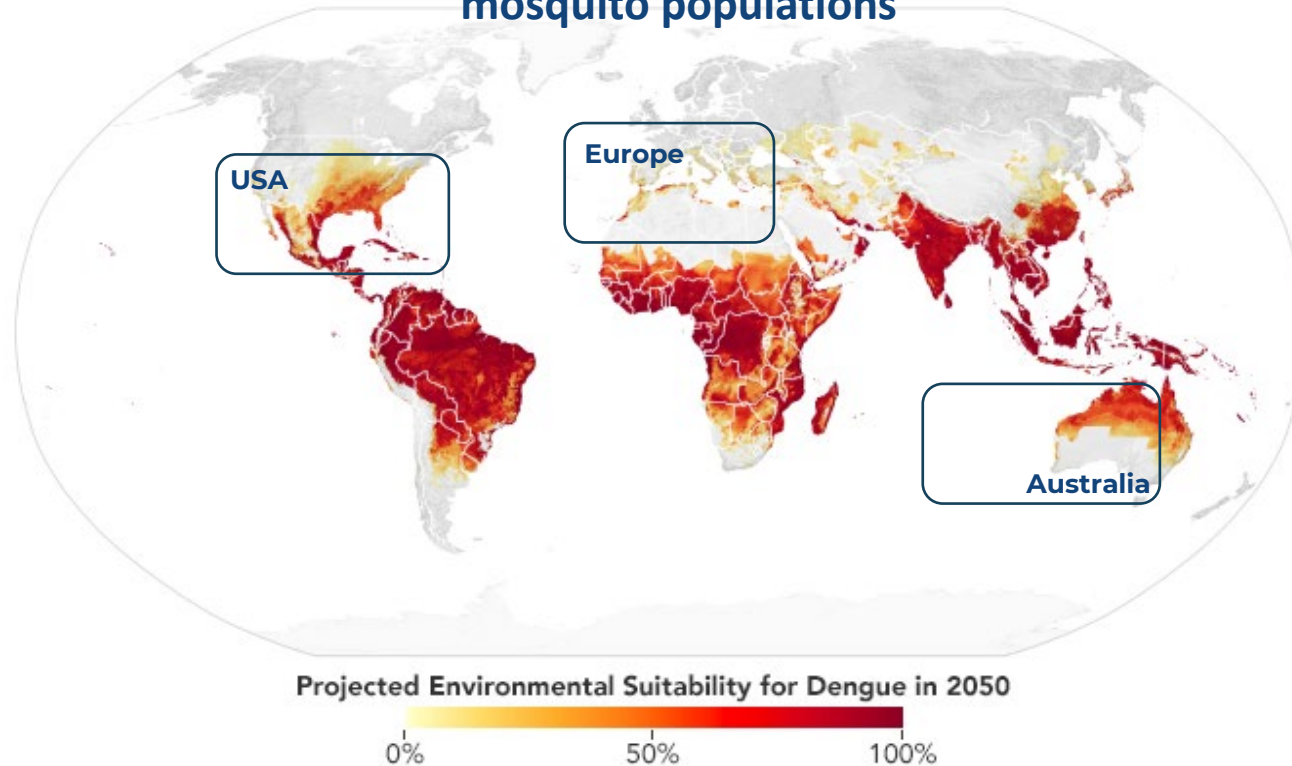
Article sources:

- <https://www.news.com.au/travel/travel-updates/travel-stories/deadly-viral-infection-doubles-in-popular-tourists-spots-for-aussies/news-story/fc32fa4fc37eeled4ca48a4deb44f51c>
- <https://shorturl.at/NsvwY>
- <https://www.nbcnews.com/health/health-news/dengue-fever-climate-change-mosquitos-tropical-disease-rca149366>
- <https://www.euronews.com/health/2024/04/24/france-warns-of-surge-in-imported-dengue-cases-ahead-of-olympics>

# DENGUE IN 2050 – A GLOBAL DISEASE



WHO 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>

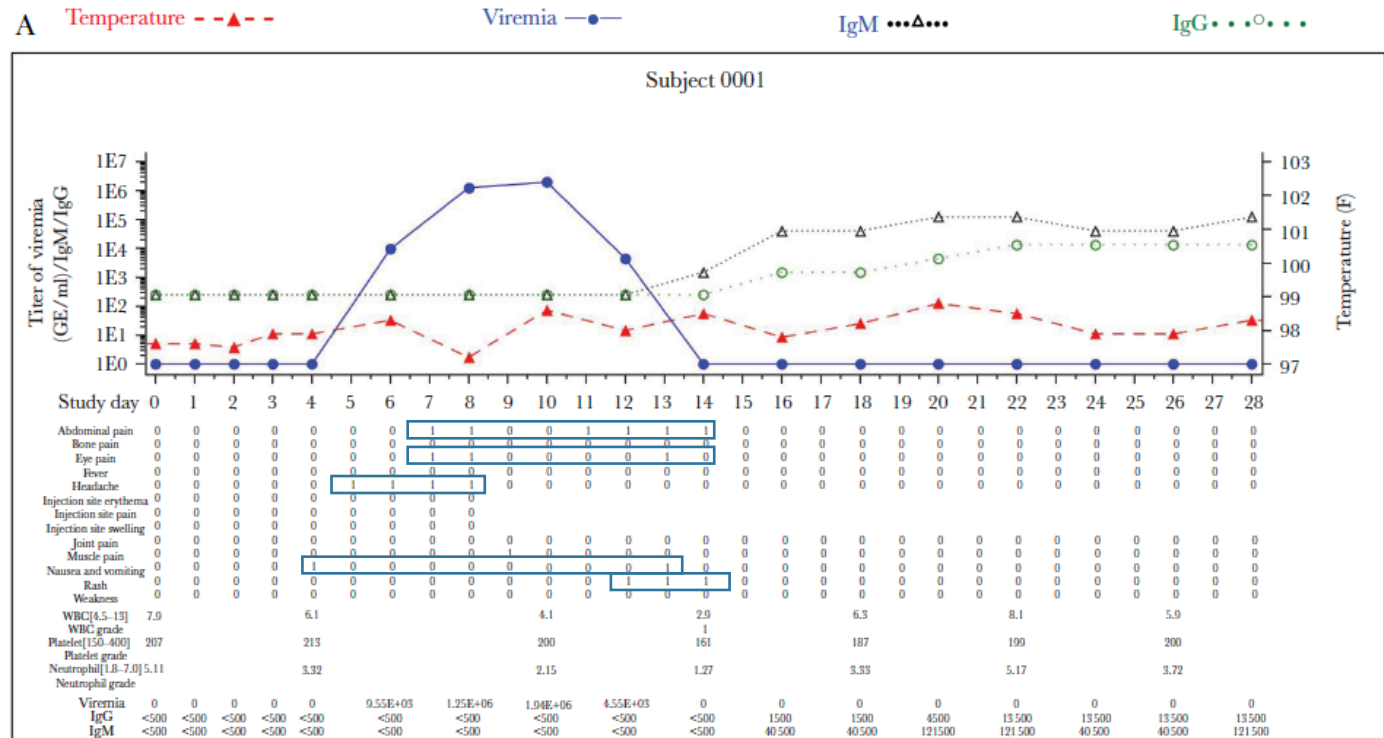
# US ARMY CRADA PROVIDES CONTROL GROUP FOR PHASE II STUDY (AND SUBSTANTIAL % OF PHASE II TRIAL COSTS)



P1 challenge study conducted by Walter Reed Army Institute of Research and SUNY is ILA's P2 study control data, and enables unprecedented ability to monitor dengue symptoms, including:

- Abdominal & eye pain
- Fever
- Headache
- Nausea and vomiting
- Rash

Island will use the same attenuated virus and approach in its current Phase 2 study.



Endy et al, J Inf Dis 2021



# TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET



## GALIDESIVIR – Ebola, Marburg, Zika & and most other RNA viruses

- 12 month, non-binding term sheet signed 3 July 2024 (AU)
- Phase I human safety data
- Proven protective efficacy in a number of lethal animal models
- If proceed to full option agreement, would be seeking to confirm continued access to FDA's **Animal Rule**
- Extensive US government funding to date
- PRV eligible (multiple options)



# COMMERCIAL OPPORTUNITIES



## BOTH candidates have prophylactic and therapeutic potential



### Travelers

Malaria is also a mosquito borne disease and therefore a proxy for other tropical diseases. Market for anti-malarials is expected to reach US\$1B<sup>1</sup> by 2026



### Government Stockpiles

Potential for countries to establish civilian and military drug stockpiles as happens with influenza.



### Military

Relationship with US Army in place (CRADA, ISLA101). Will continue discussions as programmes advance. Proven interest in both assets.



### Priority Review Vouchers

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



### National Outbreaks

Millions of patients in Latin America & Asia offer potential for sales in disease suppression and treatment during outbreaks of dengue, Zika. Increasing rapidly elsewhere.

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



# CORPORATE SNAPSHOT



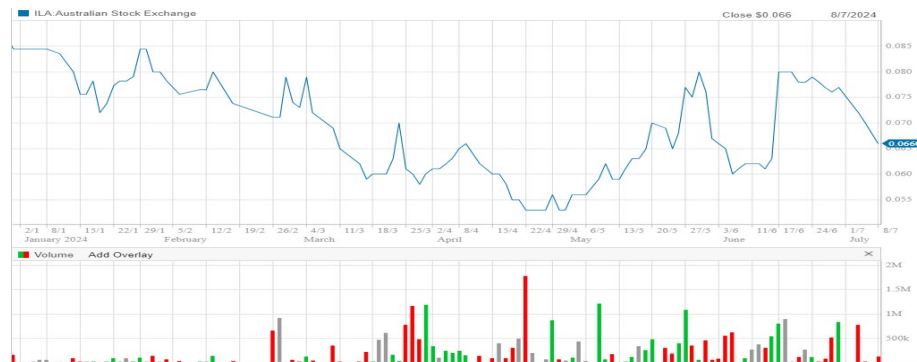
## Key data

Share price (AUD <sup>1</sup> )	\$0.066
Market cap <sup>1</sup>	\$8.37m
Shares on issue <sup>1</sup>	126,767,093
Listed Options <sup>2</sup>	32,506,360
Cash <sup>3</sup>	\$1.6m

## Board of Directors

Dr Paul MacLeman, Executive Chairman
Dr David Foster, CEO and Managing Director
Dr David Brookes, Non-Executive Director
Mr Albert Hansen, Non-Executive Director
Dr Anna Lavelle, Non-Executive Director

## Recent ILA trading history



## Substantial shareholders

Shareholder	Ownership <sup>4</sup>
Mr Jason Alan Carroll	24,100,000 (19.01%)
Dr William James Garner	22,056,105 (17.40%)
Albert Hansen / Kesa Partners	11,104,034 (8.68%)

## Ownership breakdown

- Top 20<sup>1</sup>: 72.3%
- Board and management<sup>1</sup>: 13.3%

## DoD grant funding

- USD \$625k to directly support the Phase 2

1. As at 8 July 2024 | 2. [ILA Option terms](#): Exercise price of \$0.06 expire 14 March 2025. | 3. As at 31 March 2024 – does not take into consideration cash burn since March 2024 or cash received from options exercised | 4. Shares held per ASX lodged substantial holder notices | Share price data sourced from asx.com.au

# UPCOMING MILESTONES\*\*



## 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 P1 cohorts

## H2 FY 2024 (Jan – Jun 2024)

- ✓ Dose final Single Ascending Dose study subject
- ✓ Single Ascending Dose study read out
- ✓ FDA interaction on Phase 2 study protocol
- ✓ Pipeline expansion efforts
- ✓ Complete in silico modelling of multiple dosing regimen

## H1 FY 2025 (Jul – Dec 2024)

- Obtain ethics approval for Phase 2 trial
- **Initiate Phase 2 trial**
- First patient dosed in Phase 2 trial
- Advances through Phase 2 study cohorts
- **Ongoing DD on Galidesivir program**
- **Ongoing discussions with potential partners**

## H2 FY 2025 (Jan – Jun 2025)

- Data readout from Phase 2 study
- End of Phase 2 meeting anticipated with FDA
- Plans announced for next steps in clinical program
- Progress Ebola program
- Ongoing discussions with potential partners

\*\* Dates are indicative only, based on best estimates at the time of writing; subject to change.

# Island Pharmaceuticals (ASX: ILA)



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# SCIENTIFIC ADVISORY BOARD



**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 from Monash University.



**Prof Stephen Thomas MD**

US WRAIR – SUNY Upstate 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**

BMS – Mayo Clinic  
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.

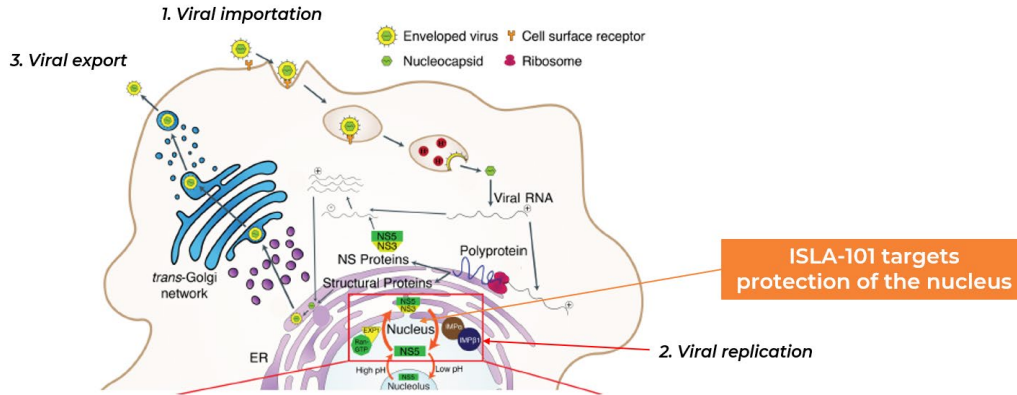
Previously, Dr. Patick has served as Vice President, Research at Adamas Pharmaceuticals, Vice President, Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, Inc. and Research Scientist at Bristol-Myers Squibb Company. Dr. Patick has also served as President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

# ISLA-101 PREVENTS VIRAL REPLICATION



## Mechanism of action (how it works)

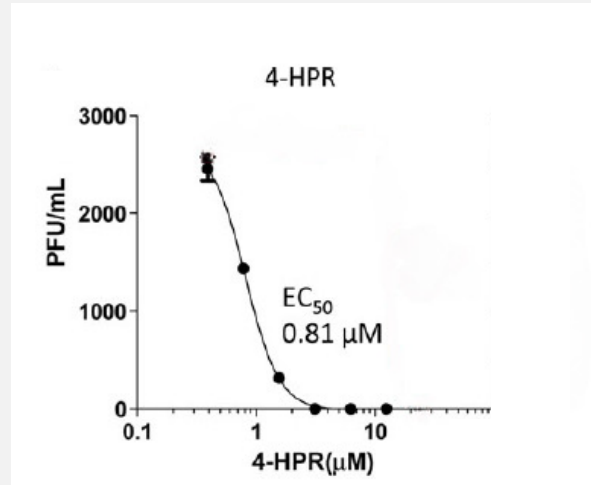


## ISLA-101 inhibits propagation of flaviviruses

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

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

## ISLA-101 reduces viral load<sup>1</sup>



Above: dose response showing ISLA-101's ability to protect against dengue infection

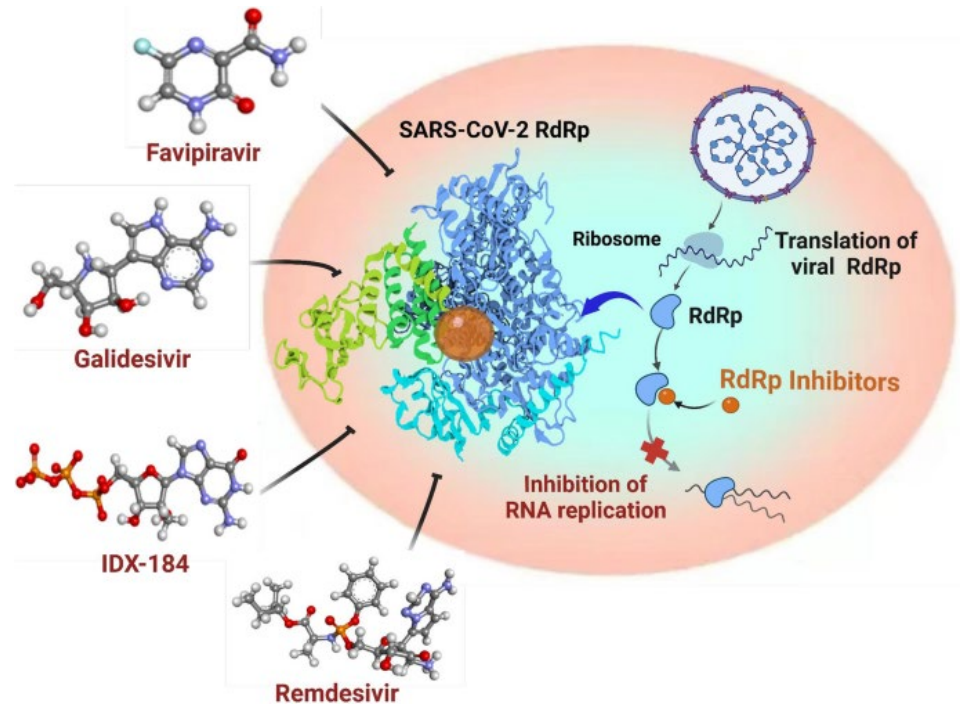
- In freshly isolated human cells, ISLA-101 was shown to potently reduce viral infection with a sub micromolar  $\text{EC}_{50}$
- Island's SAD study was designed to also investigate the ability to achieve appropriate blood concentrations in healthy human volunteers (slide 16)

# GALIDESIVIR PREVENTS VIRAL REPLICATION



## Galidesivir inhibits propagation of RNA viruses

- RNA-dependent RNA polymerase (RdRp) is crucial in viral replication and transcription
- Catalyses viral RNA synthesis and is the therapeutic target of Galidesivir



<https://link.springer.com/article/10.1007/s41061-023-00432-x>



