

**3 June 2024**

## ASX Announcement

### **New data leads to proposed ISLA-101 Phase 2 study efficiencies**

- New modelling data confirms predicted ideal single dose for coming ISLA-101 Phase 2 clinical study
- Single Ascending Dose study outcomes, combined with this new data potentially obviates the need to conduct the Phase 2 study at multiple doses, enabling streamlining of resources and cost
- Data is now being compiled as part of a broader package for submission to the US Food and Drug Administration (US FDA)
- Submission package includes proposed protocol which expands from pure prophylactic focus to also include a therapeutic arm, substantially increasing potential patient impact and market opportunity

MELBOURNE Australia, 3 June 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; “Island”; “the Company”) is pleased to announce new data, which is expected to introduce significant, quantifiable time and cost savings into the Company’s clinical program in dengue fever.

On 16 April 2024 and 22 April 2024, Island reported that its 24 patient Single Ascending Dose study in ISLA-101 had successfully achieved all study outcomes relating to safety and dosing which would enable the company to move forward with next steps regarding its Phase 2 study.

New in silico dose modelling was conducted after the Single Ascending Dose study close. While Island initially expected to need to take a multiple ascending dose approach with its coming Phase 2 study, the modelled data confirms with specificity the single level, multi-day dose of ISLA-101 which is predicted to achieve effective blood concentrations above those shown to be effective at arresting the dengue virus in prior pre-clinical studies. These findings inform the coming trial, reducing the patient dosing variables and making the study design more streamlined and informative.

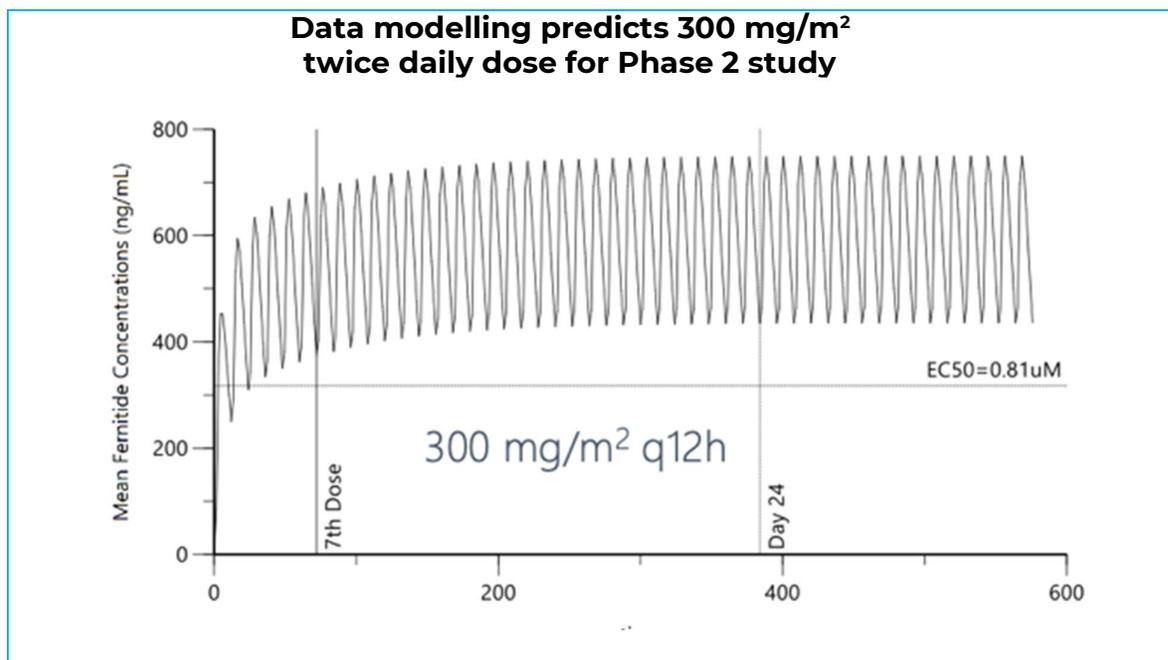
CEO and Managing Director, Dr David Foster commented, *“This final piece of data from the dose escalation study confirms what we’ve seen and reported to date. While we previously announced achieving the appropriate blood concentration following a single dose of ISLA-101, the results from this new modelling suggest that the blood concentration will increase upon repeat dosing, resulting in blood concentrations that exceed the concentration demonstrated to be effective in pre-clinical studies.*

*This opens up potential efficiencies that substantially derisk our Phase 2 program and give us great confidence that we've designed a trial that should be successful."*

### Data summary

The new simulation data highlighted that the dosing regimen planned for the Phase 2 challenge study is predicted to maintain steady state blood concentrations, higher than the concentration demonstrated for ISLA-101 to be effective against the dengue virus when measured against freshly isolated human cells (the most relevant pre-clinical study.)

In prior publications the EC50, which is a measure of the effective concentration of a drug, for ISLA101 against dengue 1 virus was 0.81  $\mu$ M. The modeling data demonstrates that using the dose planned for the Phase 2 study results in a blood concentration of at least 1.5  $\mu$ M, well above the EC50 of 0.81  $\mu$ M. This, combined with data demonstrating that ISLA-101 effectively protects against dengue infection in rodent models when dosed at lower human equivalent doses, substantially de-risks the upcoming Phase 2 study.



Importantly, when combined with the human data from the recent Single Ascending Dose study, this new modelling has enabled Island to select, with a high degree of confidence, a single dose to take into the coming Phase 2 study. Where previously this study was planned as a multiple ascending dose study, the ability to conduct the study at a single dose introduces significant safety, time and cost efficiencies.



## Expansion of application potential for ISLA-101 and next steps

The new modelling data is being compiled, together with a broader data package, for submission to the US Food and Drug Administration (US FDA). This data package includes a final study report from the Single Ascending Dose study, as well as an updated Investigator Brochure and revised clinical protocol for the Phase 2 challenge study. The protocol revisions, which will be submitted to the FDA, propose to eliminate a dose escalation strategy in view of the results obtained in the Single Ascending Dose study. Instead, the proposed study will include administering a single dose across multiple days.

Dr David Foster said, *"In the revised protocol we are also proposing to include both a prophylactic and therapeutic arm as opposed to the previously proposed prophylactic arm, substantially increasing the data we obtain from the study. This strategy increases the optionality of the program as we look to subsequent clinical trials, significantly expanding our potential to help dengue fever patients, while increasing the potential market size for ISLA-101."*

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### **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:

Jane Lowe  
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, Automatic 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.