

**16 April 2024**

ASX Announcement

## **Island reports highly positive new data from ISLA-101 Single Ascending Dose study**

- Island reports highly positive pharmacokinetic data and reconfirms strong safety / tolerability data for ISLA-101 from its 24-subject Single Ascending Dose clinical study
- Data analysis shows required levels of ISLA-101 concentration in the blood were observed after only a single dose, achieving the study's purpose
- This important new data is being used to prepare for Island's planned Phase 2a clinical trial in dengue fever

MELBOURNE Australia, 16 April 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to announce highly encouraging pharmacokinetics (PK) data from its ISLA-101 Single Ascending Dose study.

ISLA-101 is a well-known drug candidate, being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases. This new ISLA-101 PK data from the 24-subject study, is critical for determining how the drug acts in the body and for establishing appropriate dosing regimens for Island's planned Phase 2a clinical trial.

CEO of Island Pharmaceuticals, Dr David Foster said, *"This new pharmacokinetic data reinforces our strong confidence in ISLA-101. The data has shown us that even following a single dose, we are achieving blood concentrations that have previously been shown to be effective against dengue fever infections. This is exactly the outcome we hoped for - it provides a critical datapoint to underpin our dosing regimen as we prepare for the Phase 2 clinical study, which will include dosing for multiple days."*

*"We would expect from first principles to see the concentration levels increase with multiple days of dosing and this will be examined in PK modelling work that is currently being completed. We are very pleased with the outcomes of this study. It not only confirms we have an appropriate plan as we head toward Phase 2, but it has helped to build our experience with the drug, manufactured at today's standards and in a modern clinical setting."*

## Key study highlights

A drug's PK profile identifies how the body interacts with it through the duration of exposure.

Data analysis to date shows that:

- The planned doses for the Phase 2 study achieved the relevant concentrations after a single dose.
- Following a single dose, ISLA-101 achieved blood concentrations demonstrated to be effective against dengue infections.
- The concentration would be expected to increase with multiple days of dosing and this will be examined in PK modelling work that is currently being completed.
- Reinforcing the drug's safety and tolerability, in this study, Island dosed at levels equivalent to up to 10x the dose given in successful preclinical animal models (adjusted for differences in species).

## About the Single Ascending Dose study

The Single Ascending Dose study was designed to ensure that administered doses can safely achieve blood concentrations of ISLA-101 that are predicted to be effective against the dengue virus, paving the way for Island's planned Phase 2a PEACH clinical trial.

## Approved for release to the ASX by:

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## 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.