

**18 November 2024**

ASX Announcement

## **ISLA-101 Phase 2a/b PROTECT clinical trial progress update**

- **All key data samples have been collected following dosing of all subjects in the Phase 2a (prophylactic) trial as part of Island's ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever**
- **Data currently being consolidated for review by the Safety Review Committee (SRC) in the coming weeks**
- **On track to release SRC recommendation on advancing the trial to Phase 2b by end of this calendar year**

**MELBOURNE Australia, 18 November 2024:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to announce progress on its ISLA-101 Phase 2a/b clinical trial in dengue fever.

In Island's Phase 2a trial, subjects receive ISLA-101 before being infected with a weakened dengue virus developed by the US Army. The trial aims to assess whether ISLA-101 can prevent or reduce viremia and symptoms compared to a placebo, based on previous control data showing elevated viremia and symptoms in untreated subjects.

Following the announcement (ASX: 3 October 2024) that all subjects in the Phase 2a cohort of the trial had been dosed, Island confirms it has now collected the required samples to analyse how the viremia (viral load) levels in the blood of trial subjects have changed through the study. Other samples are being analysed for pharmacokinetic data as well as other blood analyses.

This data is currently being consolidated for review by the Safety Review Committee (SRC), who will meet in the coming weeks. The SRC will evaluate the safety of ISLA-101 in dengue infected individuals and consider if there is evidence of anti-dengue activity. They will then make a recommendation regarding advancing the trial to the Phase 2b cohort before the end of the calendar year.

Island's CEO and Managing Director, Dr David Foster commented, *"We are very pleased to be able to report that 46 days into the trial, we've collected the key data required for evaluation by the Safety Review Committee. From here, while we will continue to check in with patients up to 90 days post dosing, we look forward to providing all the data to the SRC for evaluation"*



*in the coming weeks. Importantly, this means we remain on track to report data before the end of the year from our Phase 2a component, and next steps for the Phase 2b cohort before the end of the year."*

Phase 2b will include 10 subjects randomised 8:2 (active: placebo) and will examine if ISLA-101 has activity as a treatment against dengue infection. This is the first time a potential countermeasure to combat the dengue virus, which afflicts more than 400 million individuals a year and for which there is no therapeutic option, is being investigated as both a preventative and therapeutic measure.

**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:**

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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, 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.