

12 February 2025

ASX Announcement

Completion of patient dosing in Phase 2b clinical trial

- **10-subject cohort successfully administered ISLA-101 in Phase 2b therapeutic (treatment) arm of Phase 2a/b PROTECT clinical trial for the treatment of dengue fever**
- **Dosing followed promising results in Phase 2a and favourable Safety Review Council review observing anti-viral activity in ISLA-101 treated subjects**
- **Subject samples now being collated and set for processing of pharmacokinetic analysis, viremia and other biomarkers of infection**
- **High-level results anticipated in the next six to eight weeks**

MELBOURNE Australia, 12 February 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to advise it has completed subject dosing for the Phase 2b therapeutic (treatment) arm of the Company's Phase 2a/b PROTECT clinical trial utilising ISLA-101 to combat dengue fever.

Pleasingly, the ten subjects in the Phase 2b cohort were successfully administered ISLA-101 on schedule and with no delays.

The Phase 2b arm of the PROTECT trial is designed to assess if ISLA-101 can reduce virus level and symptoms in a subject already infected with the dengue challenge virus, which is an attenuated or weakened strain of dengue.

Patient enrolment for the Phase 2b arm commenced in January 2025 following a positive assessment by the Company's Safety Review Committee (SRC) on data from Island's Phase 2a cohort, which determined that key benchmarks for safety and anti-dengue activity had been met (refer ASX announcement: 27 November 2024).

The Phase 2a arm examined the prophylactic (preventative) arm of ISLA-101 in dengue fever, and the positive SRC data assessment provided the Company with a strong platform to proceed to Phase 2b trials for the therapeutic application of the treatment.

The SRC's recommendations were subsequently lodged with the US Food and Drug Administration (FDA) for the recommended 30-day review period, prior to the commencement of the Phase 2b cohort.



The primary endpoint of Phase 2b is viremia (virus load in the bloodstream) reduction in subjects. Other endpoints include confirming the safety of ISLA-101, and a reduction in the symptoms associated with dengue infection. High level results from the Phase 2b study are anticipated to be available around April 2025.

Executive Chairman, Phil Lynch said: *“The opportunity for Island is both significant in scale and increasingly positive. The most recent 2a clinical results show the potential for a preventative approach to Dengue management, that could aid millions of travellers who visit exposed countries, with malaria treatment a useful analogue to quantify this opportunity.*

“We look forward to further positive results from the 2b trial, and thereafter the opportunity to progress ISLA-101 as a potential therapeutic treatment also, for what remains a significant unmet consumer healthcare need.”

- Ends -

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About Island Pharmaceuticals

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 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 for more on Island.