

22 January 2025

ASX Announcement

All subjects now enrolled in Phase 2b arm of Phase 2a/b PROTECT clinical trial

- All ten subjects now enrolled in the Phase 2b (therapeutic) cohort of Island's ISLA-101 clinical trial in dengue fever
- The Phase 2b study will explore the ability of ISLA-101 to reduce the symptoms of a person already infected with the dengue virus
- High-level results expected around April 2025; full unblinded study results from Phase 2a/b expected in Q4 FY25

MELBOURNE Australia, 22 January 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to announce that it has completed enrolment of all subjects in the Phase 2b therapeutic arm of its ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever.

The Phase 2 study is divided into two cohorts; a Phase 2a (prophylactic) and Phase 2b (therapeutic) cohort. In the Phase 2a cohort, the subjects were pre-treated with ISLA-101 before exposure to the challenge virus, which is an attenuated or weakened strain of the dengue virus, to explore if ISLA-101 can prevent or reduce infection when administered prior to exposure to the virus. In the Phase 2b cohort, Island is exploring if ISLA-101 can reduce virus level and symptoms in an individual who is already infected with the dengue challenge virus. Between the two studies, Island aims to understand if ISLA-101 can be an effective prophylactic (preventative) and/or therapeutic (treatment) against a dengue infection.

Island progressed to the Phase 2b cohort following the recommendation of the Safety Review Committee (SRC) after it reviewed data from the Phase 2a cohort and determined that ISLA-101 was safe and exhibited antiviral activity (ASX: 27 November 2024). Following submission of the SRC recommendation to the US Food and Drug Administration (FDA), and allowing for the 30 day FDA requested review period, Island initiated the Phase 2b cohort in January 2025.

Island has now completed the enrolment of all 10 subjects in the Phase 2b therapeutic arm, following enrolment of the first four subjects as announced on 8 January 2025. The final six subjects were enrolled on 21 January 2025 (US time).



Island's Managing Director and CEO, Dr David Foster, said: "*We are pleased to have reached this important milestone in our PROTECT clinical trial. The enrolment of the final six subjects in the Phase 2b therapeutic arm is a significant advancement in our clinical trial, and towards better understanding the potential of ISLA-101 as a treatment for dengue fever.*"

High-level results from the Phase 2b study are anticipated to be available around April 2025, with full results from the unblinded data of both the Phase 2a and Phase 2b cohorts expected in Q4 FY2025.

- 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 dengue2 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.