8 January 2025

ASX Announcement

Island initiates ISLA-101 Phase 2b clinical trial; enrols first subjects

MELBOURNE Australia, 8 January 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to announce the initiation of the ISLA-101 Phase 2b clinical trial, with the first subjects successfully enrolled.

Progression to the Phase 2b cohort follows the recommendation of the Safety Review Committee (SRC) after it reviewed positive data from the Phase 2a trial, which demonstrated safety and anti-dengue 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 has now initiated the Phase 2b cohort.

The Phase 2a study examined the prophylactic (preventative) arm of ISLA-101 in dengue fever, involving four subjects randomised 3:1 (active: placebo). Phase 2b is the therapeutic (treatment) arm of the trial and will involve 10 subjects randomised 8:2 (active: placebo). The first four subjects have already been enrolled, with the second group of six expected to enrol within the next two weeks.

Subjects for this therapeutic cohort will be exposed to an attenuated strain of the dengue virus, then administered either the placebo or ISLA-101 seven days post virus exposure. The primary endpoint of the Phase 2b study 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.

Island's CEO and Managing Director, Dr David Foster said: "*We are excited to start the Phase 2b cohort right on schedule, following the strong data from our Phase 2a cohort and the subsequent recommendation by the SRC to move forward. The SRC's determination that there was evidence of antiviral activity in ISLA-101 treated subjects in the prophylactic setting was a landmark conclusion and we look forward to seeing if ISLA-101 may also be effective as a treatment in dengue infected subjects. After an incredibly fruitful 12 months for the ISLA-101 clinical program, we look forward to continuing the momentum and exploring our lead drug candidate as a dengue therapeutic through the Phase 2b study*."

To subscribe to Island's monthly newsletter, IslandWatch, and other forms of email communications, please visit this page of our website.

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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[2] 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 for more on Island.