27 August 2024

ASX Announcement

Island begins patient screening for its ISLA-101 Phase 2 PROTECT clinical study

- **Institutional Review Board (IRB) approval received from US Army, enabling Island to begin screening and enrolling subjects for the PROTECT clinical trial**
- **Study structured as a Phase 2a/b and will include a prophylactic and therapeutic arm**
- **Island on track to start dosing subjects in cohort A (Phase 2a) in late September with full trial read-out expected by the end of 2024**

MELBOURNE Australia, 27 August 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to announce it has commenced screening for enrollment of subjects for its ISLA-101 Phase 2 clinical study in dengue fever following Institutional Review Board (IRB) approval from the US Army.

IRB (ethics) approval from the US Army follows earlier IRB approval from SUNY Update New York and was required because the attenuated strain of the dengue challenge virus has been manufactured by the US Army.

Earlier this month, Island received clearance from the US Food & Drug Administration (FDA) to amend the trial protocol, whereby it is now a Phase 2a/b study that includes both a prophylactic and therapeutic arm split across two cohorts. The "A" cohort (Phase 2a) is a prophylactic (preventative) arm that will include 4 subjects randomized 3:1 (active: placebo); the "B" cohort (Phase 2b) is a therapeutic arm that will include 10 subjects randomized 8:2 (active: placebo).

Island's CEO and Managing Director, Dr David Foster commented, *"IRB approval from the US Army was the final requirement in the ethics approval process and we are now working closely with SUNY Upstate New York to rapidly progress the screening and enrolling of our subjects for the Phase 2a prophylactic arm of the trial. We look forward to providing further updates once we begin dosing subjects in the coming weeks."*

Trial timing

As announced earlier this month (ASX Announcement: 7 August 2024), the FDA requested that Island wait to start infecting subjects until the end of the mosquito season (1 October 2024) to ensure the public is protected from unwanted transmission of the virus.

As the first cohort will be the prophylactic arm, Island is able to pre-treat subjects with ISLA-101 in late September and then infect them with the attenuated challenge virus on or after 1 October.

Island expects to provide a full readout of the Phase 2a cohort well before the end of this calendar year.

The Phase 2b cohort is expected to begin being dosed in January 2025.

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 theCompany's share registry, Automic Registry Services, whose contact info is housed on theShareholder Services page of the Company's website.

Visit www.islandpharmaceuticals.com for more on Island.