7 August 2024

ASX Announcement

ISLA-101 Phase 2a/b clinical trial progresses

- **ISLA-101 clinical trial protocol amendment cleared with US FDA. Study structured as a Phase 2a/b and will include a prophylactic and therapeutic arm split across two cohorts**
- **Phase 2a/b clinical trial to be renamed PROTECT: short for PROphylactic and TrEatment Challenge Trial**
- **IRB approval received from SUNY Upstate Medical Hospital in Syracuse, NY enabling advertisement to healthy volunteers to commence**
- **Enrolment will begin as soon as IRB approval is received from the US Army with prophylactic dosing expected in late September**
- **Trial costs reduced substantially – full Phase 2a/b now expected to cost around US$1.08m.**

MELBOURNE Australia, 7 August 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to announce positive progress on its ISLA-101 clinical program in dengue fever.

Following its 3 July 2024 progress update announcement, Island filed its final Single Ascending Dose Clinical Study Report from the recently completed Phase 1 clinical study with the US Food and Drug Administration (US FDA). On the same date, Island filed the proposed protocol for the upcoming ISLA-101 Phase 2 Clinical Study.

The trial protocol amendment proposed that ISLA-101 would be administered at a single dose level, twice daily across multiple days. They also included the proposal that both a prophylactic (preventative) and therapeutic arm be included in the study, as opposed to just the previously proposed prophylactic arm.

Protocol amendments cleared; trial renamed the PROTECT Phase 2a/b study

All protocol amendments have been cleared by the US FDA and the protocol has been revised to include 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).

To reflect the new (prophylactic and therapeutic) trial strategy, the Phase 2a/b study has been renamed PROTECT, which stands for PROphylactic and TrEatment Challenge Trial. The study has been registered with Clinicaltrials.gov under the identifier: NCT06528457.

As part of the consultation process on the protocol, the FDA requested that Island wait to start infecting subjects until the end of mosquito season, which occurs on October 1. This measure is designed to ensure that the public is protected from unwanted transmission of the virus by mosquitoes. Island notes that this year there have been no recorded instances of

a dengue-carrying mosquito in the part of New York, where the trial will be conducted, though fully agrees that keeping the public safe is of utmost importance and has therefore modified the trial approach to be ready on October 1.

Since the first cohort will be the prophylactic (prevention) arm, Island will be pre-treating subjects with ISLA-101, followed by infecting them with the attenuated challenge virus. Island plans to start dosing in late September and will start infecting on or after October 1.

It is expected that this timing will enable Island to provide a full readout of the Phase 2a cohort well before the end of this calendar year. The Phase 2b cohort will begin being dosed in January 2025.

Ethics process

Island has received approval from the Institutional Review Board (IRB), i.e. ethics committee, at SUNY Upstate New York. Receipt of this approval enables SUNY to advertise for the recruitment of healthy volunteers for the PROTECT Phase 2a/b clinical trial.

As Island and SUNY will be administering an attenuated strain of the challenge virus which has been manufactured by the US Army, Island must also receive IRB approval from the US Army before Island can screen and enrol healthy volunteers. Steps required to achieve this approval are underway.

Trial costs substantially reduced

On 8 May 2024, Island announced that US$625k (A$962K) in funding from a Congressionally Directed Medical Research Programs grant has been allocated by SUNY Upstate New York to directly supporting the coming ISLA-101 clinical study. In view of this grant to cover trial costs, the remaining cost to Island for the full study is around US $1.08m, which is substantially lower than prior estimates.

CEO commentary

Island's CEO and Managing Director, Dr David Foster, commented, *"We are very pleased to have now locked down our protocol for the ISLA-101 PROTECT study and have it registered, in preparation for final ethics approvals. We have worked hard to bolster our internal capabilities and as a result have not needed to engage a CRO for this study. This strategy not only has streamlined efforts on protocol revisions, FDA communications and trial execution, but has substantially reduced costs enabling us to complete the Phase 2a, prophylactic cohort of the PROTECT study with existing funds."*

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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.