

3 October 2024

## ASX Announcement

# Island doses Phase 2a subjects in its ISLA-101 Phase 2a/b PROTECT clinical trial; investors invited to 8 October webinar

- Island has dosed subjects in the prophylactic arm (Phase 2a) of its Phase 2a/b PROTECT clinical trial
- Study structured to include both a prophylactic (Phase 2a) and therapeutic (Phase 2b) arm
- The attenuated strain of dengue will be administered to subjects on 4 October 2024, with read-out from Phase 2a expected by the end of 2024 and Phase 2b expected to commence in January 2025
- Investor webinar scheduled for Tuesday 8 October at 10.30am (AEDT) to discuss latest trial developments

**MELBOURNE Australia, 3 October 2024:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to announce it has dosed all subjects in the Phase 2a component of its ISLA-101 Phase 2a/b clinical trial in dengue fever.

The study, known as PROTECT, is a cutting edge clinical trial design that capitalises on years of research by the U.S. Army to develop an attenuated strain of the dengue virus, which can be used to examine a dengue infection in a highly controlled setting. The challenge virus causes a mild but clinically relevant dengue infection in the enrolled subjects.

Island's trial design is a Phase 2a/b human challenge study that includes both a prophylactic and therapeutic arm split across two cohorts. Phase 2a is a prophylactic (preventative) arm that will include 4 subjects randomised 3:1 (active: placebo); Phase 2b is a therapeutic arm that will include 10 subjects randomised 8:2 (active: placebo). This is the first time a potential countermeasure to combat the dengue virus, which afflicts more than 400 million individuals a year and for which there is no therapeutic option, is being investigated as both a preventative and therapeutic measure.

Following dosing, the 4 subjects in Phase 2a will be administered an attenuated strain of dengue fever on 4 October 2024. From the date of infection, symptoms of all trial subjects will then be monitored for 90 days, where investigators will study the viremia curve for each subject and a range of other potential symptoms, regularly associated with dengue fever. Data from the Phase 2a study is expected well before the end of 2024 and



Island then expects to commence the Phase 2b therapeutic arm of the study in early 2025.

Island's CEO and Managing Director, Dr David Foster commented, "Dosing the Phase 2a subjects in this powerful Phase 2 PROTECT clinical trial is a pivotal moment for Island. We are weeks away from understanding the potential impact of our drug ISLA-101 on dengue fever. As the first company in the world to investigate an agent as both a prophylactic and therapeutic against dengue in a clinical setting with a challenge virus, we are proud to be conducting this innovative trial to find a preventative and/or treatment for this devastating virus, at a time when infection rates are rapidly growing around the globe."

#### Investor webinar

Island is pleased to invite shareholders and potential investors to attend an online investor briefing on Tuesday 8 October at 10.30am (AEDT).

Island Executive Chairman, Dr Paul MacLeman and CEO and Managing Director, Dr David Foster will provide a detailed update on the latest developments for the ISLA-101 Phase 2 PROTECT clinical trial, as well as an overview of recent company developments including the proposed acquisition of antiviral molecule, galidesivir.

To attend the online investor webinar, please register via the link below: <u>https://us02web.zoom.us/webinar/register/WN\_B4gPTEpUSUqQ7Ot3oZm</u> <u>Mww</u>

Once the registration form is completed, investors will receive a confirmation email detailing how to access the briefing.

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

### Approved for release to the ASX by:

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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<sup>2</sup> 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 <u>www.islandpharmaceuticals.com</u> for more on Island.