

### **15 December 2022**

# **ASX Announcement**

# Institutional Review Board approval received for ISLA-101 Phase 2a clinical trial

 Institutional Review Board approval received, subject to clearance of Island's Investigational New Drug application

MELBOURNE Australia, 15 December 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to announce that Institutional Review Board approval has been granted for the ISLA-101 Phase 2a PEACH¹ clinical trial, to be undertaken at SUNY Upstate University in New York.

The PEACH study is a Phase 2a Randomized, Double Blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model. Institutional Review Board approval in the United States is analogous to Human Research Ethics Committee (HREC) approval in Australia. It is an important regulatory requirement, necessary for trial commencement.

The approval has been provided, pending clearance of Island's Investigational New Drug (IND) application by the United States Food and Drug Administration. The IND is currently in the final stage of completion and is expected to be filed in December 2022.

Island's CEO and Managing Director, Dr David Foster commented, "We are delighted to have received this conditional approval for the ISLA-101 Phase 2a clinical trial. It is another important box that we have ticked in the lead up to the start of the trial, and one that puts us in good stead for once we have an open IND."

The Company will keep investors across progress as it nears closer to the commencement of the Phase 2a ISLA-101 clinical trial.

## Approved for release to the ASX by:

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<sup>&</sup>lt;sup>1</sup> The PEACH study is a Phase 2a Randomized, Double Blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model.



### **About Island Pharmaceuticals**

Island (ASX: ILA) is a mid-clinical-stage drug repurposing company, focused on the topical area of antiviraltherapeutics for 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. The Company is close to commencing a Phase 2a clinical trial in dengue-infected subjects.

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