

20 January 2023

ASX Announcement

Island Pharmaceuticals receives FDA feedback on IND for ISLA-101 Phase 2a clinical study

MELBOURNE Australia, 20 January 2023: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; “Island”; “the Company”) announces that it has received feedback following FDA review of the Investigational New Drug (IND) application submitted for its ISLA-101 Phase 2a PEACH¹ clinical trial (ASX announcement: 28 December 2022.)

As part of the feedback, the FDA has specified that amendments to the protocol may be required and support for, or modifications of, the proposed dosing schedule may be necessary.

In the meantime, the IND has been placed on Clinical Hold, with a formal hold letter to be issued by the FDA within the next 30 days. Upon receipt of the letter, Island will work closely with the FDA to resolve the issues as quickly as possible. This may require Island providing written responses and potentially meeting with the FDA to discuss amendments.

Island’s CEO and Managing Director, Dr David Foster said, *“We appreciate all feedback from the FDA on the trial, and will work quickly and constructively to address the Administration’s feedback. As soon as we have a material update, we look forward to sharing the next steps on the ISLA-101 program with the market.”*

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Approved for release to the ASX by:

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¹ The PEACH study is a Phase 2a randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral (ISLA-101) in a Dengue Challenge model.



About Island Pharmaceuticals

Island (ASX: ILA) is a mid-clinical-stage 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 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 www.islandpharmaceuticals.com for more on Island.