1 February 2023

ASX Announcement

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

MELBOURNE Australia, 1 February 2023: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") announces that it has received additional feedback following FDA review of the Investigational New Drug (IND) application submitted for its ISLA-101 Phase 2a PEACH[1] clinical trial (ASX announcement: 28 December 2022.)

The letter from the US FDA notes that Island's IND had been placed on Clinical Hold, as previously reported. The FDA letter further clarified that amendments to the protocol and IND will be necessary to advance the program. In addition, more data to support the proposed dosing regimen will be required. Data will be obtained in a small single ascending dose clinical trial that measures blood concentration of ISLA-101, following administration increasing doses of ISLA-101. The aim of this study is to ensure that administered doses can safely achieve blood concentrations of ISLA-101 that are predicted to be effective against the dengue virus.

Island is working with vendors and consultants to formulate the most efficient clinical plan and to understand related timing. The Company anticipates that the trial will be conducted in Australia, which will enable the trial expenses to be off-set by R&D tax credits.

Island's CEO and Managing Director, Dr David Foster said, *"We appreciate the feedback from the FDA on the trial and understand their primary focus is safety of trial participants, which we agree is of critical importance. The feedback in this letter provides very clear feedback on next steps, and we are in the process of working through the plan and associated timelines.*

In view of the vast body of data associated with ISLA-101 we anticipate that the results of the ascending dose trial will be positive, and that we will be able to advance the PEACH Phase 2a clinical trial once this preliminary study has been completed and data analysed. We look forward to keeping the market updated as the study plans and timing are confirmed."

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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.

Approved for release to the ASX by:

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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[2] 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.