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ASX Announcement Island submits responses to FDA questions for ISLA-101

MELBOURNE Australia, 17 April 2023: Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA) is pleased to provide an update on its ISLA-101 program. Island's lead asset, ISLA-101 is being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases.

Following feedback from the United States Food and Drug Administration (US FDA) on Island's Investigational New Drug (IND) submission for ISLA-101 (ASX announcements: 20 January 2023 and 1 February 2023), Island has formally filed its response after a review of all aspects of the original IND submission.

As part of its response, Island has completed a major body of work in drafting the protocol for the Single Ascending Dose study. Partners have been identified to support the study, including a Clinical Research Organisation that can run it and an analytical laboratory to test and analyse blood samples collected. An Australian site has also been identified where the study can take place. Island has expanded its access to pharmacokinetics and regulatory affairs expertise to increase the likelihood that planned responses will meet the FDA requirements in order to proceed.

Island's CEO and Managing Director, Dr David Foster said, *"We have moved as quickly as possible to file this response with the FDA to address Clinical Hold items. As a next step we will turn to navigating the remaining Non-Clinical Hold issues raised in the original feedback to our IND submission."*

Dr Foster continued, "There remains a strong unmet need for dengue fever therapeutics. The Island team is dedicated to bringing ISLA-101 forward for the treatment of dengue fever and looks forward to updating the market as soon as possible."

The FDA will review Island's response over the next statutory 30 (calendar) day period, within which time they are required to respond. Island will notify the market once it has received the outcome.

Approved for release to the ASX by:

Dr Paul MacLeman
Executive Chairman
Island Pharmaceuticals Ltd
info@islandpharmaceuticals.com

Investors and media, for further information, please contact:

Jane Lowe
IR Department
Mobile: +61 411 117 774
jane.lowe@irdepartment.com.au



About Island Pharmaceuticals

Island (ASX: ILA) is a clinical-stage drug repurposing company, developing 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 moving rapidly into clinical trials for 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.