16 May 2023

ASX Announcement
Island receives FDA go-ahead for ISLA-101 program

- Clinical Hold lifted and Investigational New Drug clearance received for the ISLA-101 clinical program by the US Food and Drug Administration (US FDA, FDA)
- Additional regulatory engagement is being planned to further optimise next steps around clinical program
- Island is now able to proceed with the Single Ascending Dose study requested by FDA

MELBOURNE Australia, 16 May 2023: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is delighted to announce that clearance has been received from the US FDA for its ISLA-101 Investigational New Drug application, and that the previously announced Clinical Hold has been lifted, enabling clinical progress to proceed. (See prior announcements dated: 20 January 2023, 1 February 2023 and 17 April 2023.)

Island's lead asset, ISLA-101 is being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases.

Lifting of the Clinical Hold will allow the Company to proceed with the Single Ascending Dose study requested by the FDA. In line with this, Island intends to open further dialogue with the FDA to steer next steps on the development program.

CEO of Island Pharmaceuticals, Dr David Foster said, *"We are extremely pleased to have received Investigational New Drug application clearance from the FDA. With the clinical hold now lifted from the program, we can proceed with taking next steps to get ISLA-101 into the clinic via the Single Ascending Dose study.*

"We anticipate being able to optimise and potentially streamline protocols for subsequent studies using input from the Single Ascending Dose study. Given this, we will seek opportunities to further engage with FDA to ensure we maximise all opportunities for adding value through efficient advancement of ISLA101 and better patient outcomes."

About the Single Ascending Dose study
Data will be obtained via a small single ascending dose clinical trial that measures blood concentration of ISLA-101, following administration-increasing doses of ISLA-101. The aim of the study is to ensure that administered doses could safely achieve blood concentrations of ISLA-101 that are predicated to be effective against the dengue virus. The Company anticipates that the study will be conducted in Australia, which will enable the trial expenses to be off-set by R&D tax credits.

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.