

## 28 October 2022

## ASX Announcement ISLA-101 manufacturing progress

- Manufacture of ISLA-101 clinical drug product is complete, pending final testing
- Minor change in timeline to IND submission and commencement of Phase 2a PEACH study in Dengue fever.

MELBOURNE Australia, 28 October 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") provides an update regarding the ISLA-101 clinical trial product manufacturing campaign for the Company's Phase 2a clinical trial in dengue fever.

Island is pleased to announce that both ISLA-101 active and placebo clinical material for the upcoming PEACH clinical trial have been manufactured and are undergoing required final analysis and stability studies.

Initial trial batches produced using historic methods yielded softgels with poor physical characteristics. As such Island determined that alternative shell formulations should be pursued. This involved revising the capsule composition such that it would deliver a superior quality product. Analytical results obtained from preliminary softgel batches prepared with the improved formulation were positive, giving Island confidence that the stability of the clinical batches will be successful.

The process of reviewing and implementing the improved formulation led to a minor extension to the manufacturing process timeframe. Importantly, at this stage, there is only expected to be a small impact on the overall trial schedule. The Investigational New Drug application submission is now expected to be filed in December 2022, with the trial opening in January 2023.

CEO of Island Pharmaceuticals, Dr David Foster said, "There is significant benefit to Island spending the extra time to improve the gelatine shell of the clinical material. We expect to come out with a product with improved characteristics and one that is very stable - this is important as we move toward clinical trials. We look forward to providing a further update once we have finished the analytical evaluation of the manufactured batches of placebo and active product."

## 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 mid-clinical-stage drug repurposing company, focused on the topical area of antiviral therapeutics 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 toobtain 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.