

**3 July 2024**

ASX Announcement

## **Island Provides ISLA-101 Clinical Program Update**

**MELBOURNE Australia, 3 July 2024:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to provide an update on the continued momentum around the Company's ISLA-101 clinical program in dengue fever.

Following several months of preparation, Island is now scheduled to file the final Single Ascending Dose Clinical Study Report from the recent clinical study with the US Food and Drug Administration (US FDA) on 3 July 2024, US time. On the same date, Island will file a proposed updated protocol for the coming ISLA-101 Phase 2 Clinical Study.

As highlighted in Island's recent announcement and investor presentation (ASX: 3 June 2024), in view of the promising dose-finding results obtained in the recent Single Ascending Dose study, the protocol revisions propose to eliminate the originally planned dose escalation strategy, in favour of a single dose level, administered twice daily across multiple days. It also includes a proposal that both a prophylactic (preventative) and therapeutic arm is included in the study, as opposed to just the previously proposed prophylactic arm.

Island will wait 30 calendar days while the FDA reviews the revised protocol, before initiating the ISLA-101 Phase 2 clinical trial.

In parallel, the Island Clinical team is scheduled to conduct the site initiation visit with SUNY Upstate New York on 11 July 2024, US time. This is the first step in trial commencement.

Once the protocol is finalised, Island currently expects to begin screening and enrolling subjects in August 2024.

CEO and Managing Director, Dr David Foster commented, *"The team has put in a major effort to finalise both our data package for the Single Ascending Dose study and revised protocol for our upcoming Phase 2 study. Both are scheduled to be submitted for FDA review tomorrow, 3 July, US time. I am grateful to all involved."*

*Given our investigational new drug application is open, and we have our clinical team and investigator lined up, once we have concluded the protocol amendment process, we plan to move quickly to commence our Phase 2 study in dengue fever."*



*Executive Chair, Dr Paul MacLeman added, "We are encouraged by the pace at which the ISLA-101 Phase 2 trial preparation is moving. I look forward to discussing our ISLA-101 progress as well as other announcement from earlier today on the non-binding term sheet to acquire infectious diseases small molecule, galidesivir, with investors at the Bioshares Conference in Fremantle, Perth next week."*

### **Bioshares conference information**

Any investors interested in meeting with Island at Bioshares are invited to contact us using the details below. Dr MacLeman is presenting as part of Session 4: Repurposing Existing Pharmaceuticals, from 5.10pm - 5.30pm on Friday July 11.

More information on the Bioshares conference is available here: <https://www.bioshares.com.au/summit/18th-bioshares-biotech-summit-1?EventGuid=8d415f38-3333-4b9d-ae86-89de1692ba5d>

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### **Approved for release to the ASX by:**

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### **About Island Pharmaceuticals**

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Island (ASX: ILA) is a 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<sup>2</sup> fever and other mosquito (or vector) borne diseases.

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, Automatic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.*

Visit [www.islandpharmaceuticals.com](http://www.islandpharmaceuticals.com) for more on Island.