23 April 2025

ASX Announcement

Phase 2a/b PROTECT clinical trial update: Treatment cohort follow up concluded with data receipt expected shortly

- **Phase 2a/b PROTECT trial using ISLA-101 in dengue fever completed with high level results to be reported next month**
- **Pharmacokinetic data from Phase 2b cohort received – dosing regimen achieved target blood concentration in all participants**
- **Island anticipates receipt of final virus level data this month**
- **Database anticipated to be locked two-weeks after receipt of antiviral data for analysis prior to results being released**

MELBOURNE Australia, 23 April 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to provide the following update on the Company's Phase 2a/b PROTECT trial using lead candidate, ISLA-101 in dengue fever.

Trial overview and progress:

Island's Phase 2a/b PROTECT trial includes two patient cohorts. The Phase 2a arm examined the prophylactic (preventative) arm of ISLA-101 in dengue fever in four subjects randomised 3:1 (active: placebo). Phase 2b involves 10 subjects, randomised 8:2 (active: placebo) and will assess if ISLA-101 can reduce virus level and symptoms in subjects already infected with the dengue challenge virus, a weakened strain of dengue virus developed by the US Army.

During Phase 2a (preventative), the trial's Safety Review Committee (SRC) deemed ISLA-101 safe and exhibited evidence of anti-dengue activity (refer ASX announcement: 27 November 2024). The SRC noted that blood levels of ISLA-101 were as desired, and given positive safety and antiviral signals, recommended that Island proceed with the Phase 2b (therapeutic) cohort.

The SRC's recommendation was submitted to the US Food and Drug Administration (FDA) as requested by the regulator, which led to the commencement of the Phase 2b cohort. Island subsequently completed Phase 2b enrolment and dosing on schedule and with no delays (refer ASX announcement: 12 February).

Follow up procedures necessary to obtain samples to analyse primary and secondary endpoints for the Phase 2b cohort have also been successfully completed.

Data obtained and pending results:

Island has received pharmacokinetic (PK) data from the Phase 2b (treatment) cohort, which showed target blood concentration in all subjects was achieved.

Data to examine virus levels from both Phase 2a and 2b is expected by the end of this month. Upon receipt and analysis of this data, the Company anticipates locking the study database within around two weeks, after which all data will be unblinded.

Following close consultation with regulatory advisors and Island's scientific consultants and given the short time period between receipt of data and locking the database, the Company has decided to not undertake an interim readout following receipt of this data. Moreover, the FDA has not requested an interim review of data, in contrast to their request following the Phase 2a (prevention) cohort. This will serve to maintain its data integrity, preserve statistical power of the results and have a positive impact on future engagement with regulatory bodies.

Island expects that high level, unblinded data for both cohorts will be reported to before the end of next month.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"We are very pleased to provide this update on the Company's Phase 2a/b PROTECT trial, which has the potential to show ISLA-101's utility in both preventative and therapeutic endeavours against the dengue virus."*

"Following completion of patient follow up for Phase 2b cohort, I am pleased to advise that the trial was executed to the highest standard, per our protocol which was previously approved by the US FDA. Further to this, the receipt of initial PK data has shown that desired target blood concentration of ISLA-101 was achieved in Phase 2b participants, similar to what was observed in Phase 2a subjects."

"We expect to receive the required data to examine virus levels in patients from both Phase 2a and b cohorts before the end of this month, with top level unblinded results to be made available in May. Following receipt of strong interim data from Phase 2a cohort, the Board and management remain confident in the pending results and look forward to providing additional updates in the coming weeks."

- Ends -

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About Island Pharmaceuticals

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 dengue2 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 theCompany's share registry, Automic Registry Services, whose contact info is housed on theShareholder Services page of the Company's website.

Visit www.islandpharmaceuticals.com for more on Island.