25 September 2023

ASX Announcement

ISLA-101 Single Ascending Dose study update

- Preparatory work largely complete to enable the Single Ascending Dose study for Island's lead asset, ISLA-101, being developed for dengue fever
- Scientia Clinical Research appointed as clinical trial site and Beyond Drug Development to run the study as Contract Research Organisation
- Study anticipated to commence in October, presuming Hospital Research Ethics Committee approval, and complete dosing in late 2023, with read out expected in early 2024
- Study to run in Australia, enabling Island to make full use of the Research & Development Tax Incentive scheme

MELBOURNE Australia, 25 September 2023: Australian antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to share a summary of recent activities and announce an agreement key to supporting the Single Ascending Dose study for ISLA-101.

ISLA-101 is a well-known drug candidate that is being repurposed for the prevention and treatment of dengue and other mosquito (or vector) borne diseases.

About the study
The Single Ascending Dose study is a dose escalation study, in which 4 cohorts of healthy subjects will receive escalating 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.

Subjects are expected to receive increasing doses of ISLA-101 under fasted conditions, with the cohort receiving the highest safe dose repeating the dosing under fed conditions. After each cohort, a Safety Review Committee will review safety data and determine if it is safe to move to the higher dose.

It is anticipated to be a short study, with dosing expected to[1] commence in October 2023 and complete in late 2023, with data read out expected in early 2024. The study will be run in Australia, enabling access to the Australian Federal Government's R&D tax incentive. This study will form the basis for rapidly transitioning to Island's planned Phase 2a human clinical dengue challenge clinical trial, called PEACH[2] study.

Study partners appointed
Island has executed an agreement with Beyond Drug Development (Beyond) under which Beyond has been appointed as the Contract Research Organisation (CRO) to run the study.

Through the same agreement, Island has appointed Scientia Clinical Research as the trial site for the study. Scientia Clinical Research is based in Sydney, Australia and is an

[1] Timing presumes that Human Research Ethics Committee approval is received in or before October 2023. Timing is subject to change.
[2] The PEACH study is a Phase 2a Randomized, Double Blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model.

FDA-audited early-phase clinical trials facility, with world-class clinical trial expertise and state of the art facilities.

Island's CEO and Managing Director, Dr David Foster commented, *"We have been focused on moving the Single Ascending Dose study along as quickly as possible and are very pleased to be nearing the commencement point. Putting this agreement in place with Beyond as our CRO and naming Scientia as our clinical site are key to underpinning the study, with both organisations highly experienced in conducting studies like ours.*

Our focus now turns to pursuing ethics approval. Should all go to plan, we hope to see the first subject dosed in October, and dosing complete in this calendar year, with the study reading out in early 2024."

To support the study, Beyond and Island have executed a first Project Agreement under a Master Services Agreement. Under this agreement Beyond is responsible for the conduct of the trial as well as engaging the clinical site, Scientia. The engagement will include subject recruitment, clinical site operations, including housing of subjects during the trial, clinical operations, project management, data management and statistical analysis. The Single Ascending Dose study will be conducted in Australia, enabling Island to make full use of the Federal Government's Research and Development Tax Incentive, which offers rebates of up to 43.5% for each dollar spent on eligible research and development activities.

About dengue fever
Dengue fever is a viral infection transmitted to humans through the bite of infected mosquitoes, with severe cases leading to serious illness and death. The number of dengue cases reported to the World Health Organisation (WHO) have increased more than eight fold over the last two decades, with one modelling estimate indicating there are now 390 million dengue virus infections per year.[3]

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 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[2] 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

[3] https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue

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.

About Beyond Drug Development

Beyond Drug Development is a leading CRO based in Brisbane, Australia, with a focus on product development and early phase research. Beyond will bring to Island's study extensive industry experience, through its expert team (averaging 20 years' experience) and strong reputation in serving early to mid-stage biotech companies and established pharmaceutical companies.

Visit www.beyonddrugdev.com for more on Beyond.

About Scientia Clinical Research

Scientia Clinical Research is an FDA audited world-class early phase clinical trials facility in Sydney, New South Wales, Australia, specialising in first-in-human and first-in-patient studies, as well as single and multiple dose studies, food effect studies, drug interaction studies, ethnopharmacology, formulation studies.

It is co-located in a major research precinct with Prince of Wales Hospital, Royal Hospital for Women, University New South Wales, and the Lowy Cancer Research Centre.

Visit www.scientiaclinicalresearch.com.au for more on Scientia.