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ASX Announcement

Island Pharmaceuticals submits IND application for ISLA-101 clinical trial

MELBOURNE Australia, 28 December 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to announce that that the Investigational New Drug (IND) application for the ISLA-101 Phase 2a PEACH clinical trial has been filed with the United States Food and Drug Administration (US FDA).

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

An Investigational New Drug application is a request from a clinical study sponsor to obtain authorisation from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Island Is the sponsor for the PEACH study, a Phase 2a randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model.

Once the IND is submitted, Island must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.[1]

Island's CEO and Managing Director, Dr David Foster commented, *"After a focused effort, we are delighted to achieve this major milestone of submitting our IND to the FDA. This submission follows the recent Institutional Review Board (IRB) approval for our Phase 2a PEACH clinical trial in dengue fever, and IND clearance will be the final, critical step before we can begin the trial."*

Presuming the IND is cleared by the US FDA in around 30 days, Island's PEACH clinical trial could begin screening and enrolling subjects in January 2023.

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.[2]

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[1] https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application
2 https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue

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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[2] 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 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.