

**15 June 2022**

## **ASX Announcement**

### **ISLA-101 manufacturing and timeline update**

- **New manufacturing partner, Sofgen Pharmaceuticals (Sofgen) appointed for the supply of ISLA-101 clinical trial study drug**
- **Clinical material being manufactured in mid-August, 2022, a six-week delay from most recent estimates**
- **Agreement provides more certainty around timeline for ISLA-101 Phase 2a PEACH clinical trial in dengue infected subjects**

MELBOURNE Australia, 15 June 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; or “the Company”) announces that it has executed a new, one-off, proposal with Sofgen for the manufacture of ISLA-101 clinical material for the upcoming Phase 2a PEACH clinical trial in dengue infected subjects.

The Company has been investigating alternative manufacturers as the prior manufacturer was unable to provide the certainty required to plan effectively. Recently the prior manufacturer updated advice that suggested additional delays, at which point Island committed to pursuing Sofgen, a softgel manufacturer in Florida, owned by Procaps Group, S.A. (NASDAQ: PROC), a manufacturer with a significant presence throughout Latin America.

The new proposal contains a schedule that has ISLA-101 clinical material being manufactured in mid-August, 2022, a six-week delay from most recent estimates. Once manufactured, the material must undergo 30-day stability studies and release testing after which the Investigational New Drug Application (IND) can be finalized and filed. This is an important step, required before the PEACH clinical trial can commence.

While a delay from prior estimates, the Company is very pleased to consolidate the timeline and based on the new manufacturing agreement, it is expected that the Investigational New Drug application will be filed in October 2022 with the trial commencing in November 2022.

CEO of Island Pharmaceuticals, Dr David Foster said, “We are enthusiastic about working with Sofgen. They are a leader in softgel manufacturing and have proven to be entrepreneurial and responsive as evidenced by their rapid response times. Moreover, we are excited by their presence in Latin America – given the prevalence of dengue fever in the region, which is anticipated to be a significant market for ISLA-101. We take our manufacturing partners very seriously and would not have changed unless there was good reason to do so. We feel we’ve now got the right solution for our strong focus on moving ahead to enable the commencement of our clinical study.”

The cost of the Sofgen proposal is \$134,000 USD, roughly in line with the prior manufacturing proposal (\$169,000 USD, of which \$20,000 was paid.)



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

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**About Island Pharmaceuticals**

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

**About Procaps Group**

Procaps Group, S.A. ("Procaps") (NASDAQ: PROC) is a leading developer of pharmaceutical and nutraceutical solutions, medicines, and hospital supplies that reach more than 50 countries in all five continents. Procaps has a direct presence in 13 countries in the Americas and more than 4,900 employees working under a sustainable model. Procaps develops, manufactures, and markets over-the-counter (OTC) pharmaceutical products and prescription pharmaceutical drugs (Rx), nutritional supplements and high-potency clinical solutions.

For more information, visit [www.procapsgroup.com](http://www.procapsgroup.com) or Procaps' investor relations website [investor.procapsgroup.com](http://investor.procapsgroup.com).