9 July 2025

ASX Announcement

Portfolio expansion achieved with acquisition of Galidesivir

- **Asset Purchase Agreement fast-tracked for acquisition of Galidesivir program from NASDAQ-listed BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX)**
- **Acquisition expedited over initially planned Option Agreement following extensive and encouraging due diligence process**
- **Galidesivir is a broad acting antiviral with a robust development history and over US$70m in R&D funding to-date from the US government**
- **Initial work will prioritise application of Galidesivir to treat Marburg - may provide optionality for regulatory approval through the FDA's Animal Rule with scope to access a Priority Review Voucher (post approval)**
- **Investor webinar with Chairman, Mr Jason Carroll, and Managing Director, Dr David Foster scheduled for today at 11:30am AEST. Register at the link below:**

  https://us02web.zoom.us/webinar/register/WN_FfmxB_aXRo6yi6L9RPQWbQ

MELBOURNE Australia, 9 July 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to confirm that it has signed an asset purchase agreement (the "Agreement") for the strategic acquisition of the Galidesivir antiviral program from NASDAQ-listed BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX).

The acquisition follows a Letter of Intent (LOI) between the parties with an option for rights to the molecule (refer ASX Announcement 11 September 2024).

Following an extensive due diligence period, the Company gained considerable confidence in the Galidesivir antiviral program, which led to a strategic decision to fast track the acquisition. The closing of the transaction will occur within the next thirty (30) days.

Island's CEO and Managing Director, Dr David Foster said: *"We are very pleased to acquire Galidesivir. The acquisition provides Island with a second asset, which has a longstanding clinical development history and data of early-stage success in multiple RNA viruses – many of which do not have approved therapies."*

"The decision to move directly through to an acquisition followed an in-depth due diligence process, which has given us considerable confidence. This has included a comprehensive review of datasets and collaboration with our leading consultants to define a potential path forward for approvals."

"The Company is now focused on engaging with the US FDA to ascertain the potential to leverage the Animal Rule, which could mean that the Company may only be required to undertake one additional successful animal study in Marburg, prior to a New Drug Application."

"If so, a successful animal study could result in approval, which in turn may provide access to a Priority Review Voucher. Recent PRVs have been valued at US$100-$150m."

Chairman, Mr Jason Carroll added: *"The acquisition of the Galidesivir antiviral program is both exciting and truly transformational for Island Pharmaceuticals. Galidesivir has shown potent and extensive antiviral activity across a wide range of viral diseases including two of the world's most feared and lethal viral infections, Ebola and Marburg. Of 1,200 categorised biological agents (infectious diseases), the US CDC classifies Filoviruses (Ebola & Marburg) as one of only six Category A bioterrorism threats – those threats which pose the greatest risk to US National Security. With a 25 to 90% mortality rate and no effective treatment for those infected, acquisition of the Galidesivir program provides the Company with an exceptional opportunity to deliver an effective treatment in a high priority threat. With two high quality assets, in Galidesivir and ISLA-101, Island is well poised to advance its programs in large, high unmet need market opportunities."*

Galidesivir program overview:

Galidesivir is a clinical-stage antiviral molecule with a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Ebola, Marburg, MERS, Zika and Yellow fever – viruses with significant unmet medical needs and that may contribute to national security threats.

It is a nucleoside analog that mimics adenosine triphosphate (ATP) and inhibits viral RNA synthesis, allowing broad activity against many RNA viruses.

The program has a robust development history, underpinned in recent years by the receipt of over US$70m in funding support from the US government, which was deployed towards ongoing clinical development to target Marburg virus disease and subsequently, Yellow Fever and Ebola virus disease, including drug development, manufacturing, preclinical and clinical trial support.

At the commencement of its development pathway, the program was designed to target significant threats. It was then expanded to include other emerging infectious diseases, including MERS and Zika for emergency disease outbreaks, later evolving further to pursue other RNA viruses.

It has robust clinical trial data, with the completion of Phase 1 studies in healthy volunteers including single ascending dose and multiple ascending dose intramuscular administration studies, as well as intravenous single ascending dose studies.

The data package also included a successful non-human primate study in Marburg, which will provide a strong foundation for pending clinical trial requirements associated with the US food & Drug Administration's ('FDA') Animal Rule.

Potential regulatory fast track and next steps:

Island will now focus on utilising the FDA's Animal Rule to advance the Galidesivir program towards a New Drug Application.

The FDA's Animal Rule allows for approval of drugs in indications based on animal efficacy data, when human trials are unethical or not feasible, provided safety is shown in humans and the disease is well modelled in animals. The Company may have the opportunity to undertake only one additional animal study, prior to the submission of a New Drug Application (based on successful results).

It's anticipated that New Drug Application approval would provide the Company with access to a Priority Review Voucher ('PRV'), which is a program implemented by the FDA to incentivise drug development for neglected diseases and rare paediatric diseases. PRV's are generally valued in excess of US$150m.

Island aims to complete its maiden animal study in Marburg utilising Galidesivir within the next 12 months. Additional updates will be provided as developments materialise.

Investor webinar:

CEO and Managing Director, Dr David Foster and Non-Executive Chairman, Mr Jason Carroll will discuss the strategic rationale for the acquisition as part of the Company's broader commercialisation strategy. The briefing will be followed by a Q&A session. Questions can be submitted now to sam.jacobs@sdir.com.au or in written form during the webinar. To attend, please register via the link below.

Date and time:

11:30am AEST (9:30am AWST) on Wednesday, 9 July

Registration:

https://us02web.zoom.us/webinar/register/WN_FfmxB_aXRo6yi6L9RPQWbQ

Terms:

The transaction was completed for a base purchase price of US$550,000, comprising an acquisition fee of US$500,000 and inclusive of a US$50,000 option fee which provided Island with exclusive rights to all rights, title, and interest in the Galidesivir program.

Additional terms relating to the transaction include:

- US$500,000 upon completion of Phase 2 clinical trial
- US$1m upon approval of New Drug Application in US or equivalent or US$1.5m upon Animal Rule approval in which no Phase 2 is required
- Tiered royalties of 5-10% of Net Sales
- 25% of proceeds from sale of any Priority Review Voucher awarded due to FDA approval of the acquired program

Q&A:

What is the FDA Animal Rule?

The following statement is an excerpt from the FDA website which describes the Animal Rule.

"The regulations commonly known as the Animal Rule (21 CFR 314.600-650 for drugs; 21 CFR 601.90-95 for biologics; effective July 1, 2002) allow for the approval of drugs and licensure of biological products when human efficacy studies are not ethical and field trials to study the effectiveness of drugs or biological products are not feasible.

The use of the Animal Rule is intended for drugs and biological products developed to reduce or prevent serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological, or nuclear substances.

Under the Animal Rule, efficacy is established based on adequate and well-controlled studies in animal models of the human disease or condition of interest, and safety is evaluated under the pre-existing requirements for drugs and biological products. Products approved under the Animal Rule are critical for the protection of public health and national security."

Source: https://www.fda.gov/drugs/nda-and-bla-approvals/animal-rule-approvals

What is Priority Review?

The FDA expedites the review of drugs treating serious conditions with the potential to provide significant improvements in safety or efficacy over existing therapies. Priority Review cuts the time in which the FDA will take action on a drug's application from ten months to six.

What is a Priority Review Voucher (PRV)?

The Priority Review Voucher program is an incentive program of the United States FDA to encourage companies to develop drugs for underserved diseases. Currently these diseases are certain tropical diseases or medical countermeasures.

Upon receipt of PRV the voucher holder can either use the voucher to request Priority Review of another drug or they can sell the voucher.

What are Priority Review Vouchers worth?

PRVs have become valuable assets in the pharmaceutical industry, with an average sale price between 2020 and 2024 being approximately US$100m (source: https://kybora.com/wp-content/uploads/2024/12/Recent-Facts-Figures-related-to-Priority-Review-Vouchers-Value-2020-to-2024.pdf).

Recent transactions include Ipsen selling its rare paediatric disease PRV to a large global pharmaceutical company for US$158m in August 2024, Valneva selling its tropical disease PRV for US$103m in February 2024 and Zevra Therapeutics selling its Rare Paediatric Disease PRV for US$150m in April 2025.

How will Island fund the acquisition and Galidesivir's ongoing clinical development requirements?

The Company will utilise existing cash at bank for the upfront consideration, as well as the potential animal trial into Marburg. The Company had $4.82m cash at bank based on its last quarterly activities report (refer ASX announcement: 30 April 2025) and $3.6m placement (refer ASX announcement: 21 May 2025), with some of the funds from this placement earmarked for clinical trial opportunities for new molecules. Details around future animal studies, clinical trials and associated budgets will be made available following consultation with FDA.

What format is Galidesevir administrated in?

Galidesivir is an Intravenous (IV) infusion, which is a method of delivering fluids, including medications, directly into the bloodstream through a vein. It is a common procedure used to administer fluids, electrolytes, blood products, nutrients, or medications when a rapid onset of effect is needed. For other forms of administration new formulations may be needed, which also will serve to form the basis of new intellectual property.

Why did BioCryst Pharmaceuticals sell the program?

In recent years, BioCryst Pharmaceuticals has undertaken a strategic shift to expand its product pipeline, and solidify its position in the rare disease therapeutics market. As part of this, BioCryst's focus on antivirals was not as prominent as the pipeline expansion into rare diseases, hence the sale of the Galidesivir program.

Does Island have the skills and expertise to advance Galidesivir and ISLA-101 concurrently?

Island has developed a team of expert advisors and consultants across all drug development disciplines to advance both Galidesivir and ISLA-101. For instance, the Company actively works with CMC, Regulatory, Clinical Operations consultants as well as engages a number of strategic advisors that have a demonstrated track record in infectious diseases.

In particular, Professor Stephen Thomas MD, who was the Lead Principal Investigator for the Pfizer/BioNTech global Phase III COVID-19 vaccine trial, is a member of Island's Scientific Advisory Board.

Prof. Thomas is a world-renowned virologist and vaccinologist and has authored numerous papers and articles on dengue fever, Zika and many other infectious diseases.

Prof. Thomas is the Chief, Division of Infectious Diseases, New York Upstate Medical University; Professor of Medicine, Professor of Microbiology & Immunology, and Infectious Diseases physician-scientist from the State University of New York (SUNY), Upstate Medical University; Chief, Division of Infectious Diseases and Director, Institute for Global Health and Translational Science (IGHTS.)

He also had twenty years in the U.S. Army Medical Corps serving at the Walter Reed Army Institute of Research (WRAIR).

In addition, Dr. Amy Patick, is a member of the Scientific Advisory Board with deep expertise in antiviral drug discovery, development and viral resistance with broad know how in emerging virus epidemics and translational medicine.

Previously, Dr. Patick has served as Vice President, Research at Adamas Pharmaceuticals, Vice President, Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, Inc. and Research Scientist at Bristol-Myers Squibb Company.

Dr. Patick has also served as President for the International Society of Antiviral Research. Dr. Patick was a postdoctoral fellow in immunology at the Mayo Clinic/Foundation in Rochester, MN and received her PhD in Medical Microbiology from the University of Wisconsin, Madison.

With access to these all of these specialists, as well as the Board and management's industry knowledge and network more broadly, Island is confident that it can pursue commercialisation of both assets concurrently.

- Ends -

To subscribe to Island's monthly newsletter, IslandWatch, and other forms of email communications, please visit this page of our website.

Approved for release to the ASX by:

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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 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.