3 July 2024

ASX Announcement

Island signs non-binding term sheet with BioCryst

- **Island executes term-sheet for the acquisition of BioCryst's antiviral molecule, galidesivir**
- **Term sheet is for a one-year option to acquire the galidesivir program**
- **Galidesivir has shown antiviral activity against a range of viruses for which there are currently unmet medical needs, including Ebola, Zika and Marburg viruses**
- **The asset, which has successfully completed Phase 1 safety studies[1], offers Island another clinically advanced, Priority Review Voucher-eligible asset, in line with the company's pipeline diversification strategy**
- **Regulatory strategy may see galidesivir taken to approval using the FDA's Animal Rule pathway**

MELBOURNE Australia, 3 July 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to announce that it has executed a term sheet with global, NASDAQ-listed company BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX), to acquire galidesivir. Galidesivir is a clinical stage antiviral molecule that exhibits antiviral activity against several different viruses, including Ebola, Zika and Marburg, for which there are no currently approved therapies[1].

Under the non-binding term sheet, Island will pay BioCryst a US$50,000 fee for the option to acquire the galidesivir program with a 12 month expiry upon execution of an Option Agreement. Given the option has a 12 month expiry, no immediate additional funding is required to service this program.

CEO and Managing Director, Dr David Foster commented, "With this term sheet, we are preserving the option to, during the next 12 months, take over development of BioCryst's galidesivir program. The identification of this particular antiviral molecule follows more than three years of research from Island into a variety of molecules as part of our pipeline diversification strategy.

"In a follow-on asset to ISLA-101, we were looking for something that already had safety data. We were also seeking a small molecule which had anti-viral activity and was eligible for a Priority Review Voucher. It needed to fit in with our interest in supporting national and military preparedness, with potential to attract non-dilutive funding in support of clinical studies. We feel that galidesivir ticks each of these boxes."

[1] https://ir.biocryst.com/news-releases/news-release-details/biocryst-completes-phase-1-clinical-trial-galidesivir
https://ir.biocryst.com/news-releases/news-release-details/biocryst-provides-update-galidesivir-program

Dr Foster continued, "With demonstrated pre-clinical activity against viruses such as Ebola, Marburg and Zika, among others, galidesivir stands poised to provide broad relief for a variety of devastating disease areas. Given the high fatality rates for Ebola in particular, should we exercise the option to acquire the asset, we would be investigating all opportunities to take galidesivir to the point of approval including the potential use of the FDA's Animal Rule."

The option period will be used for Island to perform additional due diligence and consult with advisors on the optimal clinical and regulatory strategies. If the option is exercised, acquisition terms include:

- US$500,000 upon exercising of the option to acquire all rights, title, and interest in the galidesivir program.
- 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

The Company and BioCyrst have not yet executed a definitive option agreement and neither party is bound until the option agreement is executed. The Company is targeting execution of the option agreement in the quarter ending 30 September 2024.

Q&A

What are the next steps, now that you have a term sheet in place?

The term sheet has been executed following initial due diligence. Island has disclosed the term sheet in the interest of ensuring a fully informed market and an update on business development activities. The next steps involve additional diligence on the galidesivir program.

How will you fund the acquisition of this program?

Given the option has a 12 month expiry, no immediate additional funding is required to service this program. There is significant interest in seeing Island build out its pipeline with a series of assets that develop the company's value and have potential to support military preparedness efforts. The Board is investigating a number of avenues in this regard and will update the market once further diligence on the asset has been conducted.

What is the FDA's 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 preexisting 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#:~:text=The%20use%20of%20the%20Animal,%2C%20radiological%2C%20or%20nuclear%20substances.

Do you have the skills and expertise to progress both assets?

Island is fortunate to have advisors in both Australia and the US who have deep infectious disease experience.

In particular, Professor Stephen Thomas MD, who was the Lead Principal Investigator for the Pfizer/BioNTech global Phase III COVID-19 vaccine trial.

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

In addition, Dr Leigh Farrell has more than 30 years' experience in the biotechnology and pharmaceutical industry and is Head of Health Security Systems Australia, a Division of DMTC Ltd.

Dr Farrell's past appointments include: Senior Vice President, Commercial at Certara USA, Inc where he was responsible for Asia Pacific Commercial and global government engagement for the preparedness, planning and response to major health emergencies; Chairman & COO of d3 Medicine, LLC; Vice President of Business Development at Biota Pharmaceuticals Ltd, Research Manager Johnson & Johnson Research and CEO of Gene Shears Pty Ltd. Leigh holds a PhD in Biochemistry and a Bachelor of Science (Honours) from Monash University and is a Fellow of the Australian Institute of Company Directors.

Dr. Amy Patick is a scientific consultant 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.

View more on Island's Scientific Advisory Board here: https://www.islandpharmaceuticals.com/site/about/scientific-advisory-board.

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

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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 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 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.