

### 17 September 2025

### ASX Announcement

# Investor presentation: Galidesivir underpins high level survival rates in Marburg and Ebola animal studies

- Galidesivir responsible for 94% overall survival rate in Marburg-infected primates compared to 0% survival in placebo group
- 100% survival rate in Ebola-infected primates when Galidesivir was administered immediately or 48 hours post-infection compared to 0% in placebo group
- Supported by robust Phase 1 safety data from multiple ascending dose studies in healthy volunteers
- Data to support FDA engagement under Animal Rule pathway, with a potential in-person meeting next quarter to align on Marburg fast-track approval
- Underpins Island's strategy to position Galidesivir as a critical counter measure against high-priority viral threats for inclusion in government stockpiles
- Investor webinar scheduled for 11:00am AEST on Friday, 19 September 2025

**MELBOURNE Australia, 17 September 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to provide the following presentation which summarises key findings from the Company's ongoing review of the Galidesivir data package. This data will form part of Island's ongoing engagement with the US Food and Drug Administration (FDA) (refer ASX announcement: 1 September 2025), which will include a potential in-person meeting with the regulator next quarter to seek alignment on utilising the Animal Rule to fast-track approval for use in Marburg.

### Galidesivir delivers 94% survival rate in Marburg:

Results from a previous non-human primate study by BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX) (BioCryst) using Galidesivir delivered exceptional results.

During the study, Galidesivir was administered one hour, or one or two days post Marburg virus infection. This led to an overall survival rate of 94%, including a 100% survival rate when treatment began on day one or day two post infection. This is compared to the placebo group, which succumbed to infection within ~10 days, confirming lethality from infection without intervention.

These results are underpinned by robust data in more than 100 subjects including two Phase 1 studies in humans.

94% overall survival rate					
Group	Time post infection	Survival (no.)	Survival (%)		
Placebo (untreated)	-	0	0%		
	1 hour	5/6	83%		
Galidesivir treated	24 hours	6/6	100%		
	48 hours	6/6	100%		



### **Exceptional survival rates in Ebola:**

BioCryst have also undertaken two non-human primate studies to test Galidesivir's utility in Ebola. During the initial study, Galidesivir was administered immediately post-infection which led to a 100% survival rate.

A follow up study was then undertaken, during which Galidesivir was administered on day two or three post infection, followed by a maintenance dose for a further 9 days. The outcome of this study delivered a 100% survival rate when dosing began on day two and a 67% survival rate when it commenced on day three.

These results highlight that Galidesivir protected non-human primates against an otherwise lethal Ebola infection, depending on the timing of administration. The Company plans to pursue additional studies in Ebola.

Summary of historical Ebola non-human primate studies:					
Group	Survival (no.)	Survival (%)			
Placebo (untreated)	-	0/6	0%		
	Immediately	6/6	100%		
Galidesivir treated	48 hours	6/6	100%		
	72 hours	4/6	67%		

### **Investor webinar:**

Island advises that CEO and Managing Director, Dr David Foster and Non-Executive Chairman, Mr Jason Carroll will undertake a webinar to provide an overview of this data and the Company's recent progress. The briefing will be followed by a Q&A session. Questions can be submitted to <a href="https://example.com/henry.jordan@sdir.com.au">henry.jordan@sdir.com.au</a> prior, or in written form during the webinar. Anyone wishing to attend the webinar must register via the following:

- Date and time: 11:00am AEST (9:00am AWST) on Friday, 19 September
- <a href="https://us02web.zoom.us/webinar/register/WN\_9gWQ2DdVRr6cH\_GT-PeEGQ#/registration">https://us02web.zoom.us/webinar/register/WN\_9gWQ2DdVRr6cH\_GT-PeEGQ#/registration</a>

Presentation slides are available as an attachment to this announcement. The recording of the presentation will be made available following the initiative.

### **Management commentary:**

**CEO and Managing Director, Dr David Foster said**: "Over the last few weeks, the Company has continued its thorough review of the Galidesivir data package and I am very pleased to provide some of the key findings from previous studies undertaken by BioCryst."

"These historical clinical results are exceptional. Previous trials provide management with considerable confidence in our engagement with the FDA, which has the aim of potentially fast-tracking approval for use in Marburg under the Animal Rule. Further, ongoing review has also highlighted a number of other opportunities across high priority threats such as Ebola, which underpins the Company's strategy to become a trusted provider to government stockpiles."

"We remain focused on compiling all relevant data for the FDA, ahead of a proposed in-person meeting in the coming months. Alongside this, negotiations with clinical



trial sites and partners are progressing well and we look forward to providing additional updates in the coming weeks."

### Q&A:

# What differentiates Galidesivir's efficacy profile in Marburg and Ebola from other antivirals in development?

Galidesivir has delivered consistent, high survival rates in stringent non-human primate (NHP) models — including up to 100% survival in Marburg when dosed up to 48 hours post-infection and 100% survival in Ebola when dosed immediately or at 48 hours. This breadth and dosing flexibility are rare among antivirals targeting Category A pathogens.

# How robust are the NHP data, and how well do these models predict human outcomes under the FDA's Animal Rule?

The NHP models used are FDA-recognised gold standards for filovirus research, closely replicating human disease progression. This makes them directly applicable to the Animal Rule, which allows approval based on animal efficacy when human trials are not ethical or feasible.

# What is the significance of achieving 100% survival at 48 hours post-infection in Marburg models?

It demonstrates a wider therapeutic window than many antivirals. This time period may be critical in virus outbreaks or bioterror scenarios where diagnosis and treatment may be delayed.

# How broad is Galidesivir's antiviral spectrum, and which other Category A or B threats could it address?

Beyond Marburg and Ebola, Galidesivir has shown activity against Yellow Fever, Zika, and other RNA viruses in preclinical studies, supporting its potential as a multi-threat countermeasure.

# What does the Phase I safety data tell us about dosing flexibility and potential for rapid field deployment?

Phase 1 trials in healthy volunteers showed Galidesivir was well tolerated across multiple dose levels, with no serious adverse events.

# Can you walk us through the FDA Animal Rule process and where Galidesivir currently sits on that pathway?

The Animal Rule more broadly allows approval based on well-controlled animal efficacy studies plus human safety data. Galidesivir already has Phase 1 safety data and strong NHP efficacy data, which may make it eligible for approval under the Animal Rule.

Island's next step is to complete any confirmatory animal studies and finalise the regulatory package with the FDA. This process may also include a potential meeting with the FDA during the next quarter, which the Company has already requested.

# What additional animal studies, if any, are required before NDA submission for Marburg?

We anticipate one pivotal, GLP-compliant NHP study in Marburg to confirm efficacy



under FDA-agreed protocols, after which the data can be integrated into an NDA submission.

Alignment on the use of the Animal Rule for Galidesivir approval in Marburg will discussed at the Company's proposed meeting with the FDA next quarter.

# How realistic is the potential to secure a Priority Review Voucher (PRV), and what would that mean from shareholder value perspective?

Given Marburg's designation as a high-consequence pathogen with no approved treatments, a PRV is a realistic outcome upon approval. PRVs have historically sold for, up to US\$160m, representing a significant potential non-dilutive value event.

# What are the expected timelines from the planned Marburg animal study to potential FDA approval?

Subject to study initiation and FDA alignment, we estimate three months from the pivotal animal study to NDA submission, with approval potentially within six months thereafter under Priority Review.

# How large is the addressable market for Galidesivir in government stockpile programs, both in the US and internationally?

The US Strategic National Stockpile (SNS) and equivalent programs in allied nations represent a combined multi-US\$100m annual procurement opportunity for filovirus countermeasures.

# What precedent exists for multi-year Strategic National Stockpile contracts, and how might that translate to revenue potential?

Several antivirals and vaccines have secured multi-year, multi-US\$100m SNS contracts. Similar procurement for Galidesivir could provide long-term, predictable revenue streams.

# How does Galidesivir's positioning compare to other antivirals that have successfully entered the SNS under the Animal Rule?

Galidesivir's broad-spectrum profile, favourable safety data, and multiple administration routes position it competitively, with the added advantage of efficacy across more than one Category A pathogen.

# What is the partnering strategy — are you seeking co-development, licensing, or direct government procurement agreements?

We are open to strategic partnerships that accelerate regulatory approval, manufacturing scaleup, and procurement. This could include co-development with government agencies or licensing arrangements with global health organisations.

# What are the key scientific, regulatory, and manufacturing risks that could impact timelines or approval?

Risks include variability in animal model outcomes, evolving regulatory requirements, and ensuring manufacturing readiness at scale. We mitigate these through early FDA engagement, rigorous study design, and alignment with experienced manufacturing partners.



### Approved for release to the ASX by:

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#### **About Island Pharmaceuticals**

Island (ASX: ILA) is focused on areas of unmet need for drugs that can address urgent viral diseases, public health or biosecurity threats. The Company is executing a dual development strategy for its assets, ISLA-101 and Galidesivir.

ISLA-101 has a well-established safety profile, being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases. 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.

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.



# **COMBATTING URGENT VIRAL DISEASE THREATS**

Dr David Foster, CEO & Managing Director

September 2025

**ASX: ILA** 



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### **Future performance**

This presentation contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "propose", "goals", "targets", "aims", "outlook", "forecasts", "should", "could", "would", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Any indications of, and guidance on, future operating performance, earnings and financial position and performance are also forward-looking statements. Forward-looking statements in this presentation include statements regarding the Company's future growth options, strategies and new products. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions.

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Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.



# (ASX: ILA) is an antiviral therapeutics company targeting infectious diseases



Two, well advanced clinical stage programs



Major market potential via both programs



Both assets have Priority Review Voucher potential



Engagement underway with US FDA to fast track regulatory approval of Galidesivir



Positive results in aggressive models

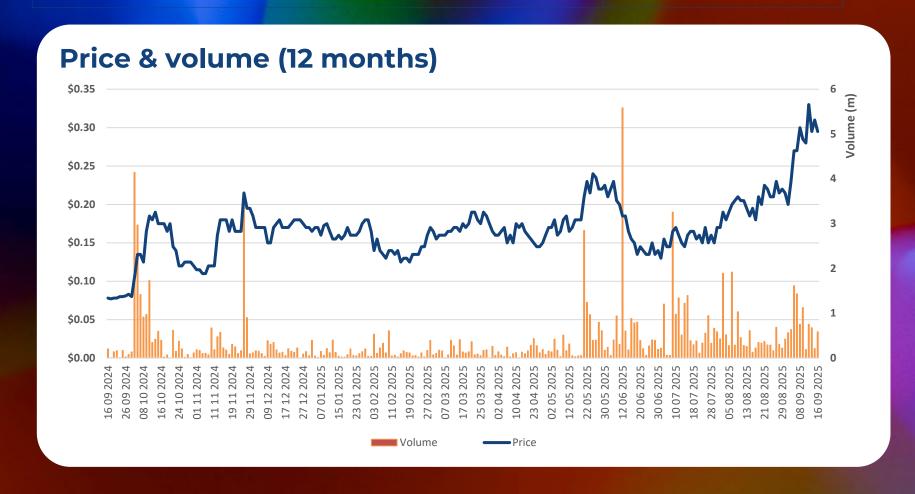


Multiple near term value catalysts

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# **CORPORATE OVERVIEW**

Share on issue¹:	253,776,761
Price per share¹:	\$0.295
Market capitalisation¹:	\$74.9m
Cash at bank (30 June 2025) <sup>2</sup> :	\$7.25m
Debt	Nil





Substantial shareholders	
Dr William James Garner³	16.86%
Jason Alan Carroll <sup>4</sup>	12.25%
MWP Partners Limited <sup>5</sup>	8.25%
Dr Daniel Tillett <sup>6</sup>	5.55%

### **Board of Directors**

Jason Carroll, Non-Executive Chairman

Dr David Foster, CEO & Managing Director

Chris Ntoumenopoulos, Non-Executive Director

- 1. As at 16 September 2025
- 2.Does not take into consideration cash used or cash received from options exercised since reporting date
- 3 Per holding per Substantial interest notice lodged with ASX on 17 July 2025
- 4.Per Director Interest notice lodged with ASX on 25 July 2025
- 5 Per holding per Substantial interest notice lodged with ASX on 3 June 2025
- 6 Per holding per Substantial interest notices lodged with ASX on 15 August 2025

Island Pharmaceuticals Limited 04



# **COMPANY OVERVIEW**

- Two clinical stage assets Galidesivir and ISLA-101 both with Priority Review Voucher potential based on approval
- Galidesivir:
  - Small molecule with broad antiviral activity against numerous high-priority threats
  - Robust development history with over US\$70m in funding to-date from US government
  - Potential to leverage FDA's Animal Rule to fast-track approval in Marburg
  - Potential to unlock government stockpile opportunities as a bioterror counter measure
- ISLA-101:
  - Pre-clinical work at Monash University highlighted antiviral promise
  - 40+ Phase I, II and III human trials in cancer and respiratory diseases, and deemed safe by regulators
  - Small molecule with activity against all 4 dengue serotypes and other mosquito borne viruses
  - Successfully completed Phase 2a/b clinical trial in dengue infected subjects
- Robust balance sheet allows for execution of program development

# GALIDESIVIR PROGRAM UPDATE



Asset overview: Multiple opportunities presented across large markets

Demonstrated activity against **20+ viruses** – many with no available treatment 2

Activity against **potential bioterror** threats

3

# Potential markets:

- Government stockpile programs
- Numerous antiviral programs
- Ripe potential for partnering



# **BROAD SPECTRUM ACTIVITY DEMONSTRATED**

Data highlights activity in vitro against multiple RNA viruses from diverse families

Virus Family	Virus	Strain/Variant	
	Marburg	Musoke	
	Marburg	Ci67	
Filoviridae	Marburg	Angola	
	Ebola	Kikwit Boniface	
	Sudan	Boniface	
	VEE	SH3	
Togaviridae		FL93-939	
Togaviridae 	WEE	California	
	Chikungunya	AF 15561	
	Rift Valley Fever	ZH501	
Bunyaviridae	LaCrosse encep	Wisc 1960	
	Maporal virus	HV97021050	
Arenaviridae	Lassa	Josiah	
Arenaviridae	Junin	Romero	

Virus Family	Virus	Strain/Variant
	Nipah virus	Malaysia
Paramyxo	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
Corona	MERS-CoV	_
Orthomyxo	Influenza	рН1N1
Picornaviridae	Rhinovirus-2	HGP
	West Nile	New York
	Yellow fever	17D
Flaviviridae	Jap. Enceph.	SA14
riavivii idae	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika	PRVABC59



# DEMONSTRATED IN VIVO ANTIVIRAL EFFECTS

Impact achieved with delayed dosing across a broad range of viruses

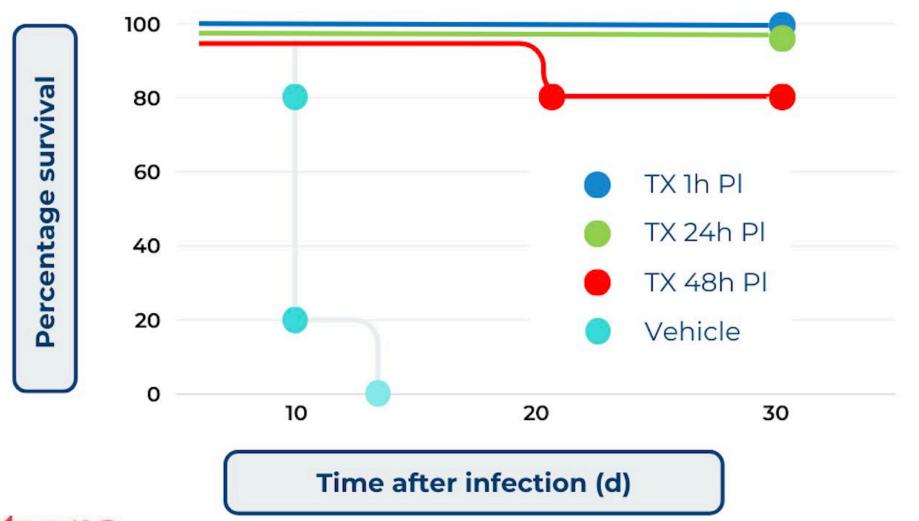
Animal Species	Virus	Dose Regimen	Key Results
Hamsters	Yellow Fever	100 mg/kg BID 7 days	100% survival initial dose 3dpi, 80% survival initial dose 4dpi²; 12.5% survival control
Rhesus NHP	Zika	100 mg/kg BID, 25 mg/kg BID 9 days	Substantial suppression of viral load following galidesivir treatment at day 3 post infection
Cynomolgus NHP	Marburg	15 mg/kg BID 14 days	100% survival initial dose 2dpi°; 0% survival control.
Rhesus NHP	Ebola	100 mg/kg BID loading, 25 mg/kg BID 10 days	100% survival initial dose 2dpi, 67% survival initial dose 3 dpi <sup>d</sup> ; 0% survival control.

Key terms		
BID Twice Daily		
2dpi	2 days post infection	
3dpi	3 days post infection	

# HIGH EFFICACY IN MARBURG NON-HUMAN PRIMATE STUDY



Treated non-human primates showed an overall survival rate of 94% during trial



- 6/6 animals survived when dosed 48 hours post infection
- 6/6 animals survived when dosed 24 hours post infection
- 5/6 animals survived when dosed 1 hour post infection

0/6 untreated animals survived as part of the control group

nature



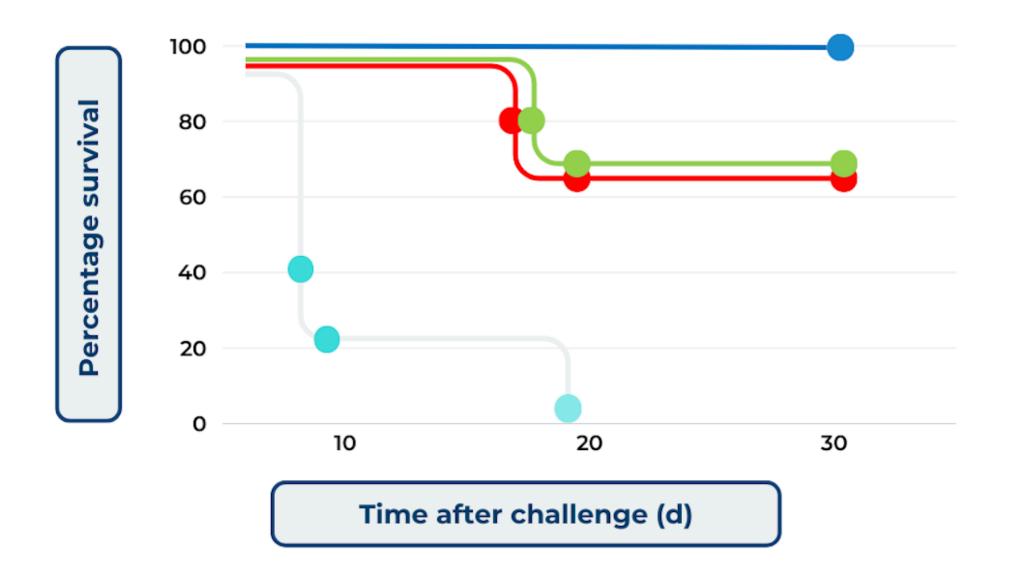
# MARBURG NON-HUMAN PRIMATE STUDY SUMMARY

Study Group	Virus	Survivors (number)	Total subjects	Survival rate (%)
Placebo	Marburg	O	6	0%
Galidesivir (1 hour)	Marburg	5	6	83.33%
Galidesivir (24 hour)	Marburg	6	6	100%
Galidesivir (48 hour)	Marburg	6	6	100%

# PROMISING EFFICACY IN EBOLA VIA NON-HUMAN PRIMATE STUDY



Treated non-human primates had an overall survival rate of 78%



- 6/6 animals survived when dosed
   48 hours post infection with loading dose
   followed by maintenance dose
- 4/6 animals survived when dosed
   72 hours post infection with loading dose followed by maintenance dose
- 4/6 animals survived when dosed
   48 hours post infection with only maintenance dose

0/6 untreated animals survived as part of the control group

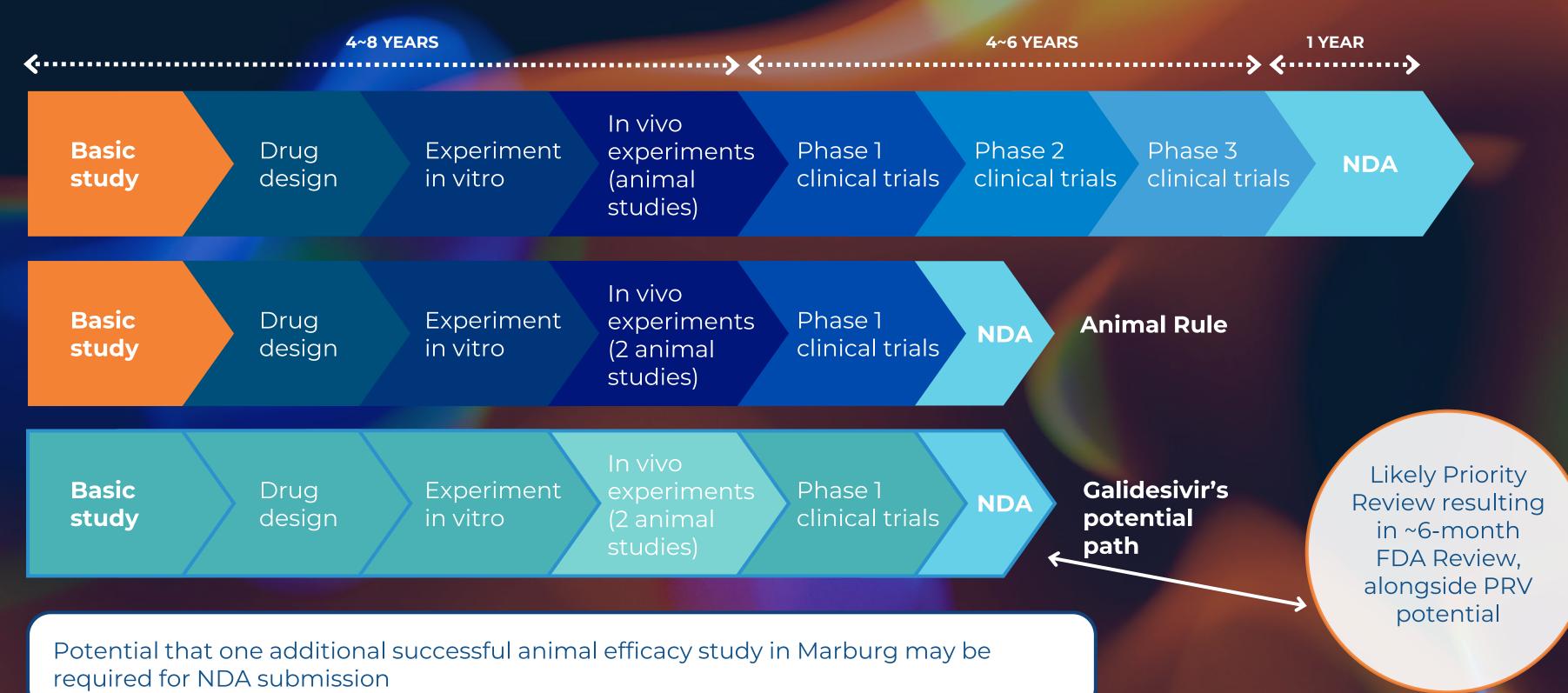


# EBOLA NON-HUMAN PRIMATE STUDY SUMMARY

Study Group	Virus	Survivors (number)	Total subjects	Survival rate (%)
Placebo	Ebola	O	6	0%
Galidesivir (48 hour) loading dose followed by maintenance dose	Ebola	6	6	100%
Galidesivir (48 hour) only maintenance dose	Ebola	4	6	67%
Galidesivir (72 hour) loading dose followed by maintenance dose	Ebola	4	6	67%



# POTENTIAL REGULATORY PATH



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# GALIDESIVIR IS DESIGNED TO PROTECT THE BACKBONE OF NATIONAL RESILIENCE

ILA's stockpile strategy ensures full treatment coverage for the 10,000+ individuals critical to outbreak containment and continuity of government – from POTUS + Cabinet to Essential Infrastructure Leaders.

Tier	Estimated Headcount	Notes
President + Cabinet	~25	Includes POTUS, VP, Cabinet Secretaries
Congressional Leadership	~50	Speaker, Majority/Minority Leaders, Committee Chairs
Supreme Court	9	All Justices
National Security & Defense Heads	~100	Joint Chiefs, DHS, CIA, NSA, FEMA, etc.
Continuity-of- Government Staff	~500-1,000	Includes designated survivors, relocation site personnel
HHS/CDC/FDA Leadership	~200	Key public health and regulatory officials
State Governors + Key Staff	~1000	50 governors + emergency response leads
Tier 1 Healthcare Response Teams	~5,000-10,000	BSL-4 lab staff, frontline responders, quarantine facility personnel
Essential Infrastructure Leaders	~2,000-5,000	Power grid, water, telecom, transport continuity

# HIGH-PRIORITY RECIPIENTS FOR **GUARANTEED TREATMENT COURSE** TIER 1 -100 President + Cabinet Congressional Leadership Supreme Court TIER 2 -300 National Security & Defense Heads Continuity-of-Government Staff • HHS/CDC/FDA Leadership -1,000 TIER 3 • State Governors + Key Staff • Tier 1 Healthcare Response Teams -10,000 TIER 4 • Essential Infrastructure Leaders • Tier 2 Response Personnel Allied Leadership • Tier 3 Response Personnel Other Critical Workers

# ANIMAL RULE IS A PROVEN PATH FOR BIOTERROR THREAT COUNTERMEASURES

	Company	Product	Year Approved	Disease Treated	SNS Sales (AUD)	Under SNS Contract
	Emergent BioSolutions	raxibacumab	2012	Inhalational Anthrax	~\$450M	Yes
	Kaléo	AUVI-Q	2012	Anaphylaxis (emergency countermeasure)	~\$100M+	No (contract expired)
	Emergent BioSolutions	BioThrax	2015	Anthrax (prophylactic vaccine)	~\$1.2B+ (multi- year)	Yes
	Elusys Therapeutics	Anthim	2016	Inhalational Anthrax	~\$320M	Yes
	SIGA Technologies	TPOXX	2018	Smallpox	~\$850M+ (ongoing)	Yes
	Paratek Pharmaceuticals	Nuzyra	2018	Anthrax (post- exposure prophylaxis)	~\$120M (partial uptake)	Yes (limited scope)
	Bavarian Nordic	Jynneos	2019	Smallpox / Monkeypox	~\$300M+	Yes
	Chimerix	Tembexa	2021	Smallpox	~\$400M	Yes

Since 2012, the FDA's Animal Rule approval has led to 8 bioterror countermeasures joining the US Strategic National Stockpile

In 7 out of 8 cases, these medical countermeasures continue to remain under SNS contract and have generated 'lifetime sales' of between US\$100m - US\$1.2Bn at an average of US\$467m

~US\$600m has been provided through grants to develop a Marburg countermeasure with no tangible results

Marburg is the only Category A biothreat that has no treatment presently available in the Strategic National Stockpile

FDA approval of Galidesivir in Marburg provides a significant opportunity for a Priority Review Voucher as well as a multi-year SNS contract

# POTENTIAL REGULATORY FAST TRACK

Existing Galidesivir data package and FDA Animal Rule unlock quicker approval path

- Data package includes successful non-human primate study in Marburg and two phase I safety studies
- FDA's Animal Rule allows for approval based on animal efficacy data when human trials are unethical or infeasible
- Animal Rule requires disease to be well modelled in animals and human safety data
- ILA may only require one successful animal study, prior to a New Drug Application with the FDA
- Approval would unlock a Priority Review Voucher worth over US\$150m
- PRV's are granted by the FDA allowing expedited review of a future drug application



## **Galidesivir transaction**

Due diligence with BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) completed and asset purchase agreement executed

## Maiden animal study

Aim to complete within 12 months from completion of acquisition

## **New Drug Application with FDA**

Submission may be based on positive animal study results

# **Secure Priority Review Voucher**

Three most recent PRV's have been valued between US\$103m - US\$158m

### **Drug development**

Focus on potential for government stockpiling agreements

# **NEAR TERM MILESTONES**



A number of value catalysts pending over the coming months for Galidesivir

Galidesivir specific milestones	Timeframe
Completion of Galidesivir transaction	Complete
Submission of documents and meeting request to FDA regarding Galidesivir	Q3 CY2025
Sign research agreement with gold-standard BSL4 facility and develop clinical trial protocol	October CY2025
Receive feedback from FDA regarding in-person meeting agreement or written responses	October CY2025
Meeting with FDA to discuss Galidesivir Animal Rule applicability	November CY2025
Initiate animal study using Galidesivir in Marburg	November CY2025
Completion of Marburg animal study using Galidesivir	December CY2025
Preparation of NDA	Q1 CY2026
File NDA with the US FDA for approval of Galidesivir as a treatment for Marburg viral infection	Q2 CY2026

Dates are indicative only, based on current estimates and subject to change



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