17 November 2025

ASX Announcement

FDA agrees Animal Rule pathway and Priority Review Voucher eligibility for Galidesivir in Marburg

Responses significantly de-risk Galidesivir regulatory pathway – Island is now the first Australian company with an opportunity to advance drug approval under the FDA's Animal Rule

- **FDA confirms the Animal Rule pathway is appropriate for developing countermeasures against Marburg**
- **FDA advises Galidesivir would qualify for a Priority Review Voucher (PRV) on approval – PRV's command prices up to ~US$155m on the open market**
- **Clear guidance provided by the regulator on clinical program design – enables Island to finalise plans ahead of trial commencement**
- **Island intends to commence the Galidesivir clinical trial program to advance approval in Q1 CY26 based on program approval by FDA**
- **Responses significantly de-risk and accelerate regulatory pathway**
- **FDA provided important feedback and confirmed the strength of historical data, including 94% survival in Marburg-infected primates versus 0% in placebo**
- **Underpins Island's strategy to position Galidesivir as a critical counter measure against high-priority viral threats for inclusion in government stockpiles**
- **Island is concurrently advancing agreements with potential trial sites and commencing US Government engagement initiatives**

MELBOURNE Australia, 17 November 2025: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to provide an update on positive responses from the US Food & Drug Administration (FDA) to questions posed in a Type C Meeting Request regarding Galidesivir's approval pathway for use in Marburg under the FDA's Animal Rule, as well as its eligibility for a Priority Review Voucher (PRV) and pending clinical development initiatives.

The Company received written responses from the FDA on 12 November 2025 (US time), which highlighted that the Animal Rule is an appropriate regulatory pathway for approval of Marburg countermeasures. Further, the regulator has stated that Galidesivir would qualify for a Tropical Disease Priority Review Voucher upon approval under the Animal Rule. A PRV is one of the most valuable incentives offered by the FDA and have previously sold on the open market for between US$100 and US$155m.

The FDA also provided valuable guidance on Galidesivir's clinical development program to advance approval. The Company has the opportunity to submit questions to FDA by 2 December 2025 (US time) requesting clarifications on this feedback. This will provide another opportunity to engage with the regulator and to optimise Galidesivir's clinical program design for the best chance of approval.

The Company is now focused on incorporating all FDA guidance into Galidesivir's clinical development pathway. This initial feedback will assist Island in preparing a study design that will be finalised alongside discussions with FDA. Once a study protocol is submitted to FDA for review, a response is expected within 30 days from submission.

Receipt of these responses follow extensive engagement with the FDA and submission of a briefing document (refer ASX announcement: 29 September 2025) which highlighted historical animal studies showing Galidesivir was responsible for a 94% overall survival rate in Marburg-infected primates compared to 0% survival in placebo group (refer ASX announcement: 17 September 2025).

Concurrently, Island is advancing a number of initiatives for Galidesivir's broader commercialisation in line with its stated strategy to position Galidesivir as a critical counter measure against high-priority viral threats for inclusion in government stockpiles. These include negotiations with potential trial sites, as well as US government engagement initiatives.

Management commentary:

CEO and Managing Director, Dr David Foster said: *"These responses from the FDA represent one of the most important regulatory milestones in Island's history and significantly de-risk the Galidesivir program from a development and commercial standpoint. Confirmation that the Animal Rule is a viable path for development of a Marburg countermeasure and that Galidesivir would qualify for a Tropical Disease Priority Review Voucher validates the strength of our existing dataset, highlights the immense opportunity in front of us and provides a clearly defined, faster path to market."*

"A Priority Review Voucher alone has the potential to generate substantial strategic and financial value for shareholders, while the Animal Rule pathway enables us to move rapidly towards approval, where traditional trials are not feasible."

"The FDA's detailed guidance on our upcoming clinical development opportunity also provides us with clarity to advance into the next phase with confidence and we remain on track to work with FDA to finalise an optimal study design."

"With strong regulatory momentum, increasing US Government engagement, balance sheet strength and a highly compelling dataset, Island is exceptionally well placed to create meaningful value as we progress Galidesivir towards approval and potential inclusion in national stockpiles."

Q&A:

What is the FDA's Animal Rule and why is it important?

The Animal Rule allows drugs to be approved based on efficacy demonstrated in well-controlled animal studies when human trials are unethical or not feasible – such as with highly lethal diseases like Marburg virus.

Galidesivir already has Phase 1 safety data and strong NHP efficacy data, supporting the strategy that approval can be gained using the Animal Rule.

Why is a Priority Review Voucher (PRV) significant?

A PRV is one of the most valuable incentives offered by the FDA. Historically, PRVs have sold on the open market for US$100~US$155m.

Confirmation of PRV eligibility significantly enhances the commercial value of Galidesivir and provides a clear financial incentive tied to its approval.

What are the next steps with the FDA?

Island is working with advisors to formulate clarifying questions to FDA that may be submitted by 2 December 2025. In addition, the Company is preparing a development plan that will include an animal study incorporating FDA's guidance. Upon completion of this plan, Island will submit this to FDA for approval.

In parallel, Island is working with Biosecurity Level 4 (BSL4) facilities where animal studies may be conducted to update them on FDA feedback and prepare for commencement of an updated animal study per FDA guidance.

Will the Company have to undertake more than one clinical trial to submit a New Drug Application for Galidesivir's approval?

It is expected that at least one non-human primate study will be required, additional determinations will be made based on pending FDA engagement and feedback.

The Company is expecting further engagement with regulatory consultants and the FDA in the coming weeks, which will assist in finalising its clinical development pathway.

Is the Company funded to undertake the next phase of clinical development?

The Company had a cash balance of $6.9m (at 30 September 2025) and has outstanding, in the money options set to expire by 4 December 2025 which are likely to be exercised to deliver another $1m in funding.

This provides the Board with a high degree of comfort in having the financial flexibility to execute on upcoming clinical development initiatives.

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.

- Ends -

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.

ISLAND PHARMACEUTICALS

Galidesivir Program update – FDA response significantly de-risks regulatory pathway

Dr David Foster, CEO & Managing Director

November 2025

ASX: ILA

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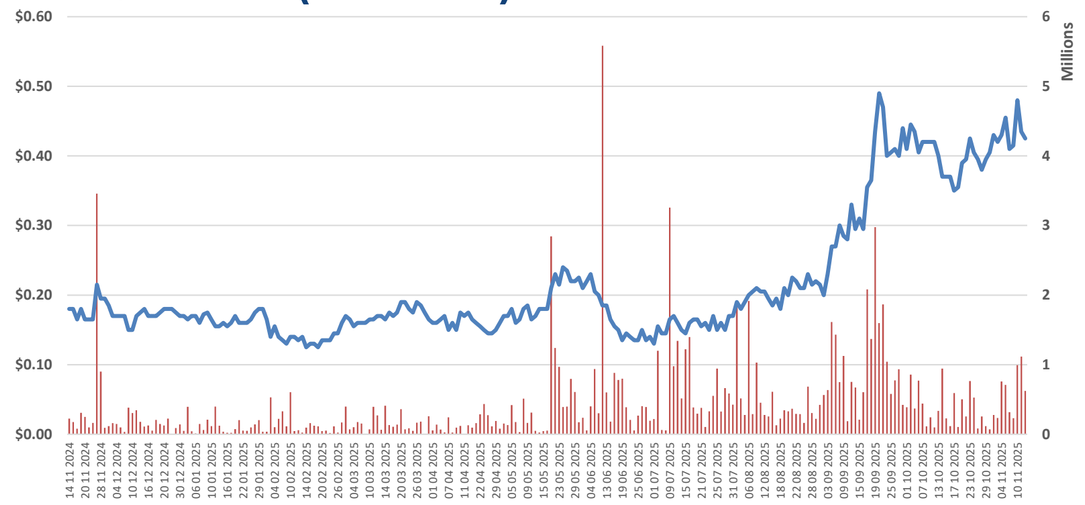
CORPORATE OVERVIEW

Share on issue[1]:	**254,623,427**
Price per share[1]:	**$0.425**
Market capitalisation[1]:	**$108.2m**
Cash at bank (30 Sep 2025)[2]:	**$6.90m**
Potential additional capital from vested options where current share price exceeds exercise price:	**~$4m**
Debt:	**Nil**

Price & volume (12 months)



Substantial shareholders	
Dr William James Garner[3]	16.86%
Jason Alan Carroll[4]	12.21%
MWP Partners Limited[5]	8.25%
Dr Daniel Tillett[6]	5.55%

Board of Directors
Jason Carroll, Non-Executive Chairman
Dr David Foster, CEO & Managing Director
Chris Ntoumenopoulos , Non-Executive Director

1. As at 13 November 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

GALIDESIVIR PROGRAM OVERVIEW

- 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
- Confirmed regulatory pathway under the FDA's Animal Rule
- Qualifies for a Priority Review Voucher on approval
- Potential to unlock government stockpile opportunities as a bioterror counter measure

1

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

FDA RESPONSE SIGNIFICANTLY DE-RISKS REGULATORY PATHWAY

Island has the potential to become to first Australian company to gain drug approval via the FDA's Animal Rule

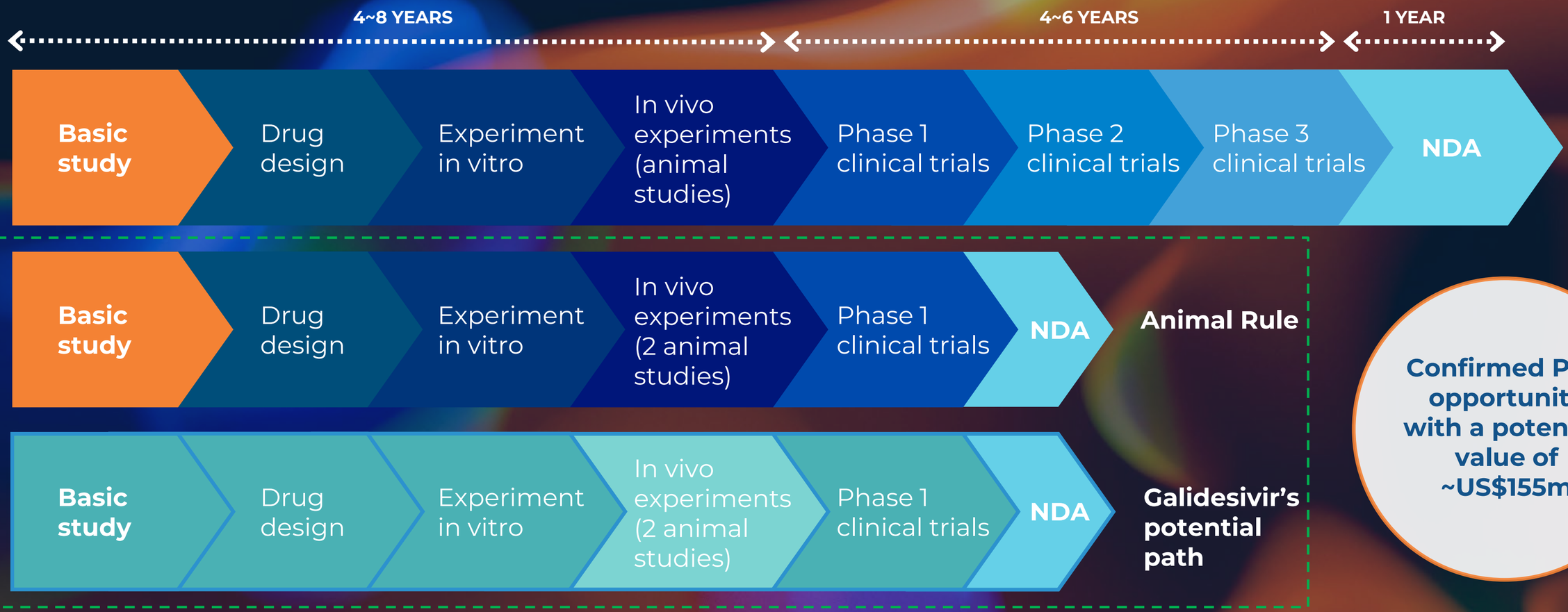
FDA confirms the Animal Rule pathway is appropriate for developing countermeasures against Marburg virus

Clear guidance provided on clinical program design – enables Island to continue to engage with the FDA and finalise plans ahead of trial commencement

FDA advises that Galidesivir would qualify for a Priority Review Voucher on approval – PRV's command open market prices of up to US$155m

Island intends to commence the final Galidesivir clinical trial program to advance approval in Q1 CY26 based on final FDA approval

POTENTIAL REGULATORY PATH



Confirmed PRV opportunity with a potential value of ~US$155m

Island is now focused on incorporating all FDA feedback into Galidesivir's clinical development pathway to finalise design and continue regulatory engagement

GALIDESIVIR PROVIDES UNPRECEDENTED SPEED TO MARKET

Feature / Category (Expanded)	Oncology Asset (Fast Track)	Galidesivir (Animal Rule)
Human efficacy trials	Multiple Phase 2 and Phase 3 trials required	No human efficacy; NHP survival data accepted
Endpoints	Surrogate biomarkers; must confirm in Phase 3	Animal survival + viral clearance validated by FDA
Safety data	Starting at Phase 1 safety only	2 Phase 1 human safety studies complete
Timeline to approval	6–10 years (even accelerated)	TBD on FDA feedback
Regulatory precedent	Common in oncology approvals	Rare (<15 approvals since 2002), all national security
Commercial outcome	Competitive market entry; slow uptake to peak year sales (PYS in ~5 years)	PRV on approval and SNS procurement (PYS in year 1)
Investor upside	Targeted patient base lowers commercial cost and increases profitability	Low commercial cost structure and high price; PRV worth US$100–160m + long-term SNS revenues

The FDA has a number of paths for acceleration of pharmaceutical compounds to approval:

- Fast Track Designation
- Breakthrough Therapy Designation
- Accelerated Approval Pathway
- Priority Review
- **Animal Rule Pathway (Special Case)**

The Animal Rule pathway is extremely rare and limited to US National Security threats

The Animal Rule pathway is regulatory hyper-track reserved for the most critical biothreat countermeasures

Marburg is the only Category A bioterror threat gap that remains unfilled within the SNS

All products approved-to-date under the FDA's Animal Rule have secured SNS contracts averaging ~US$500m in lifetime value

BROAD SPECTRUM ACTIVITY DEMONSTRATED

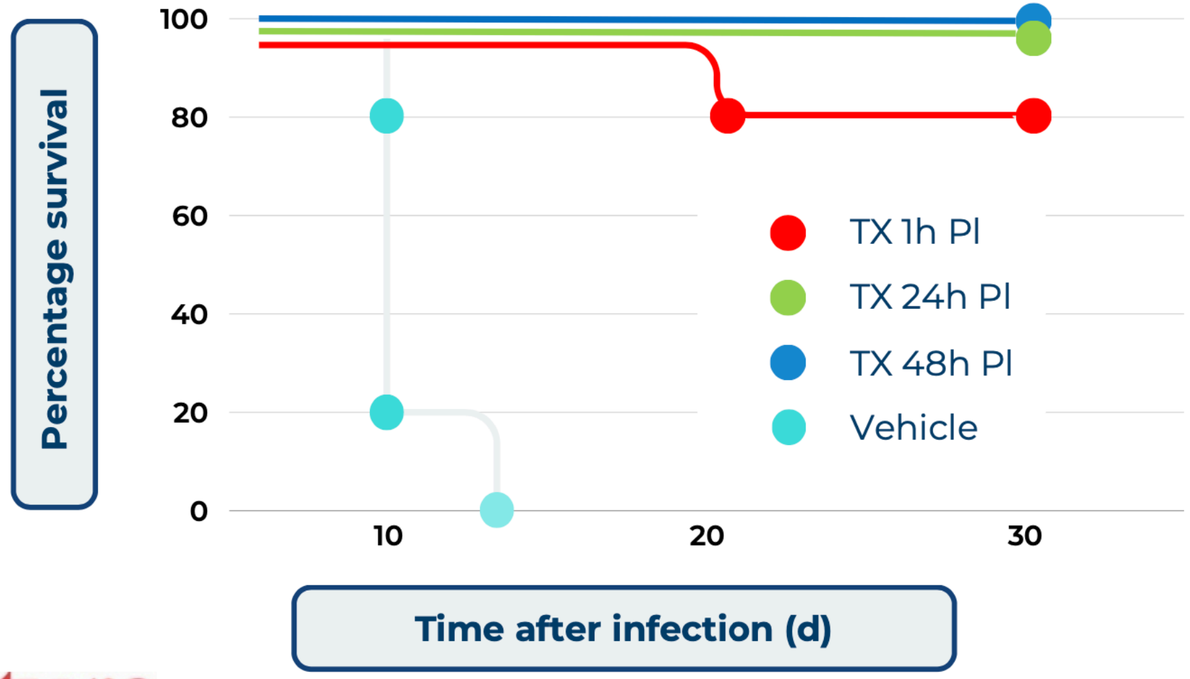
Data highlights activity in vitro against multiple RNA viruses from diverse families

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

Virus Family	Virus	Strain/Variant
Paramyxo	Nipah virus	Malaysia
	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
	MERS-CoV	Jordan
Orthomyxo	Influenza	pH1N1
Picornaviridae	Rhinovirus-2	HGP
Flaviviridae	West Nile	New York
	Yellow fever	17D
	Jap. Enceph.	SA14
	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika	PRVABC59

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	0	6	0%
Galidesivir (1 hour)	Marburg	5	6	83.33%
Galidesivir (24 hour)	Marburg	6	6	100%
Galidesivir (48 hour)	Marburg	6	6	100%

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

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

TIER 3 -1,000

- State Governors + Key Staff
- Tier 1 Healthcare Response Teams

TIER 4 -10,000

- Essential Infrastructure Leaders
- Tier 2 Response Personnel
- Allied Leadership
- Tier 3 Response Personnel
- Other Critical Workers

NEAR TERM MILESTONES

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

Galidesivir specific milestones	Timeframe
Advance US Government engagement initiatives	November CY25
Sign research agreement with gold-standard BSL4 facility and develop clinical trial protocol	Q4 CY25
Submit clarifying questions on initial FDA feedback to assist in finalizing Galidesivir clinical program	Q4 CY25
Commence strategic appointments to establish Galidesivir Advisory Committee	Q4 CY25
Prepare proposed study protocol and submit to FDA for review	Q4 CY25 - Q1 CY26
Finalise proposed study design following FDA review	Q1 CY26
Commencement of Galidesivir's clinical development prior to NDA preparation	Q1 CY26
Advance opportunities for Galidesivir's broader development in other indications	Ongoing
Explore partnership and international government engagement opportunities	Ongoing

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

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