



# INVESTOR PRESENTATION ASX: AGN

MANAGING DIRECTOR PRESENTATION  
OCTOBER 2024



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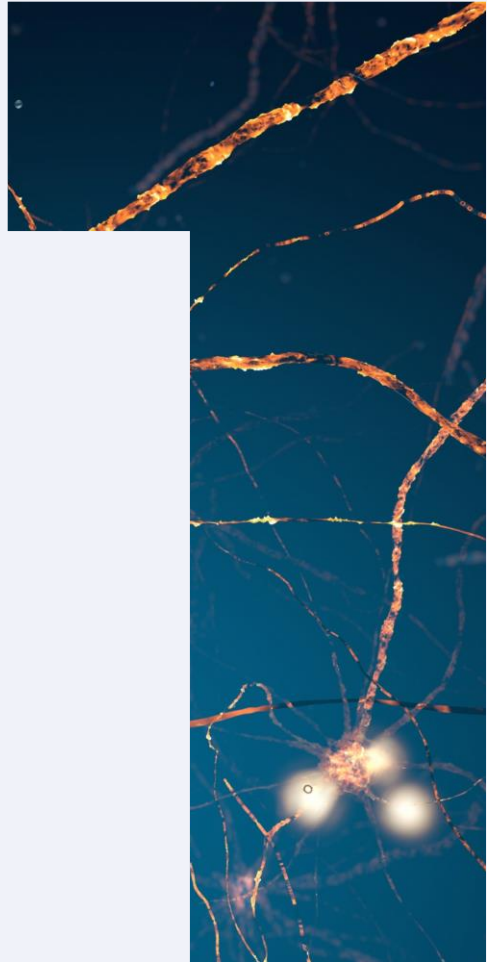
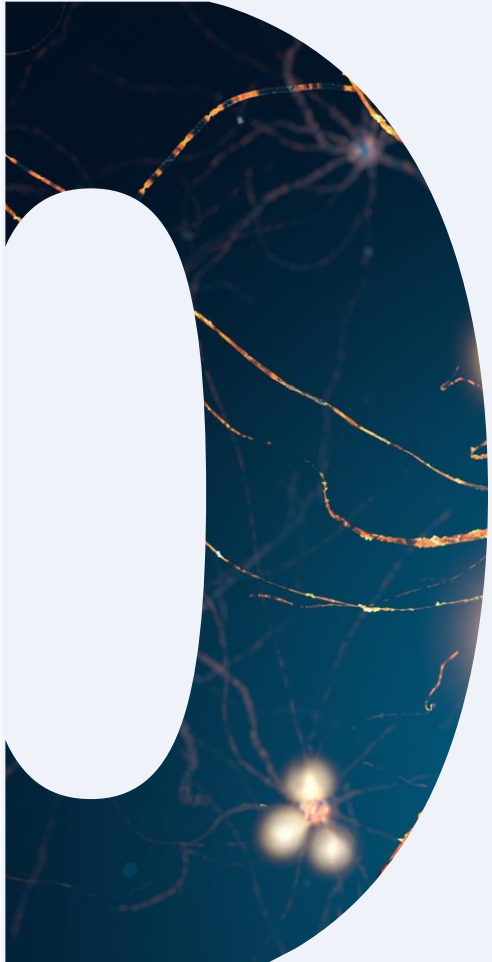
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# NEUROPROTECTION THE THERAPEUTIC OPPORTUNITY



# BREAKTHROUGH NEUROPROTECTIVE THERAPY



## MISSION

Commercialise a neuroprotective treatment that minimises brain damage and fosters recovery following stroke & other neurological conditions



## VISION

Redefine the standard of care for stroke and other neurological conditions but reducing brain injury



## IMPACT

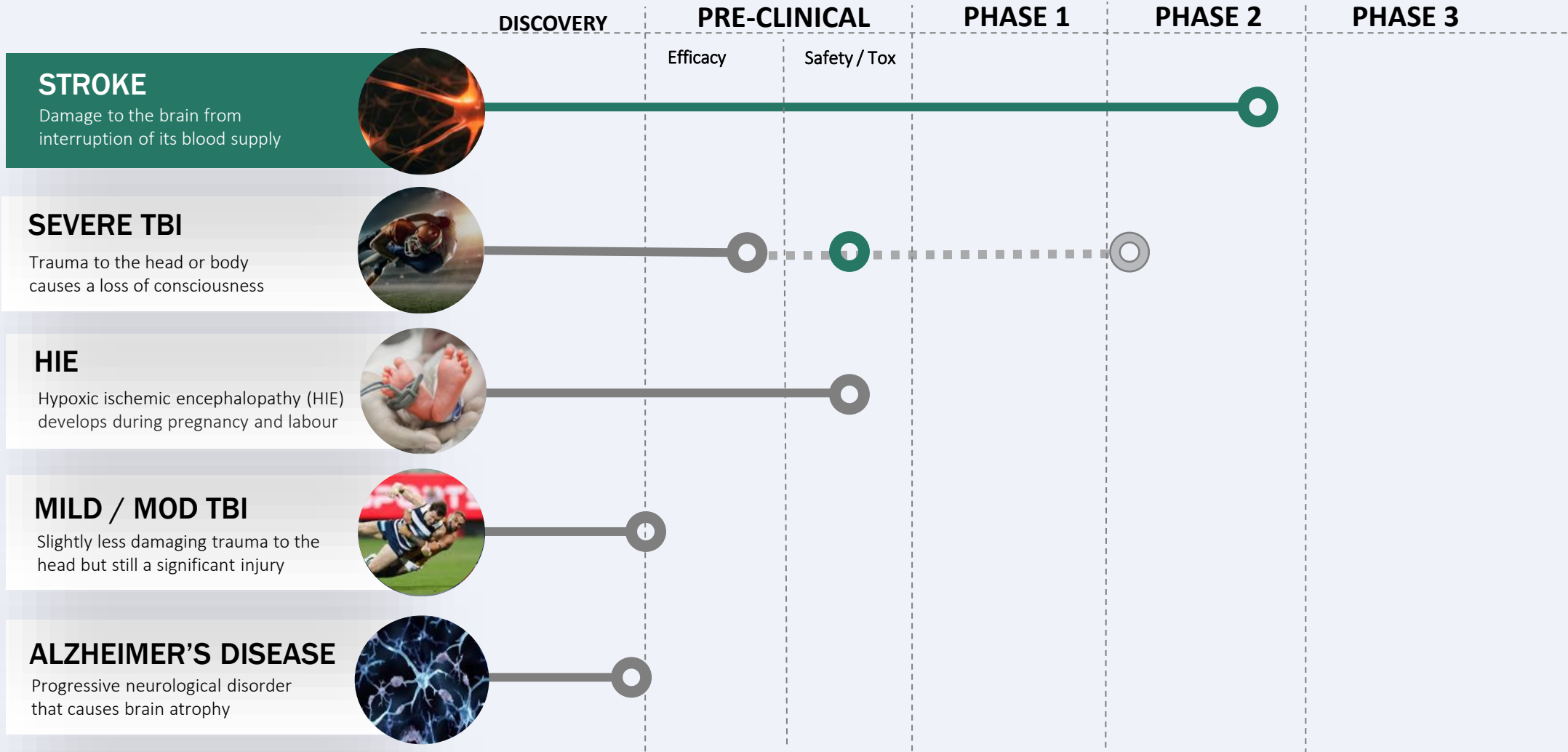
Create positive, life-altering impact for millions suffering from neurological conditions, offering new hope

## ABOUT ARG-007

- Cationic poly-arginine peptide
- Multiple mechanisms of action working across multiple conditions
- Granted patents & strong IP
- Significant pre-clinical efficacy
- 25+ peer reviewed papers
- Proven safe for healthy humans



# OUR LEAD DRUG CANDIDATE ARG-007



Single dose of ARG-007 in severe TBI can move straight from preclinical into Phase 2 clinical trial, do not need to repeat a Phase 1 or safety & tox studies.




# POTENTIAL OF ARG-007

## MAIN INDICATIONS

**STROKE** 

**TBI** 

**HIE** 

**ALZHEIMER'S DISEASE** 

Ability to partner / licence on all indications

## ADDRESSABLE MARKET

**USD\$12bn**  
by 2030<sup>1</sup>

1. Coherent Market Insights Report – Acute Ischemic Stroke (AIS) Market Analysis, Oct 2023

**USD\$18.6bn**  
by 2031<sup>2</sup>

2. Traumatic brain injuries assessment market research, 2031 – Allied Market Research

**USD\$1.9bn**  
by 2030<sup>3</sup>

3. Data Bridge Market Research Market Analysis Study 2023

**USD\$13.0bn**  
by 2031<sup>4</sup>

4. Alzheimer's Therapeutics Market Global Opportunity Analysis 2021-2031 – Allied Market Research

All indications have large addressable markets

## SUMMARY OF RESULTS TO DATE

**66% reduction**  
in Brain Tissue Death 24 hours after stroke

**70% reduction**  
in Brain Tissue Death 28 Days after stroke

**52% reduction**  
in neurofilament heavy protein

**51% reduction**  
in amyloid precursor protein

**52% reduction**  
in total brain injury 4 weeks after injury

**60% reduction**  
compared to hypothermia

**65% reduction**  
in Abeta aggregation

**84% reduction**  
in cellular uptake of a-syn

**89% reduction**  
in Tau aggregation

Results to date are exceptional and will drive commercial / partnering interest



# KEY COMPANY METRICS

**\$15.9M**  
CASH @ BANK<sup>1</sup>

**\$93.5M**  
MARKET CAP<sup>2</sup>

**+\$4M**  
NON-DILUTIVE GRANTS<sup>3</sup>

**128.1M**  
SHARES ON ISSUE

**37%**  
SHARES HELD BY TOP 20

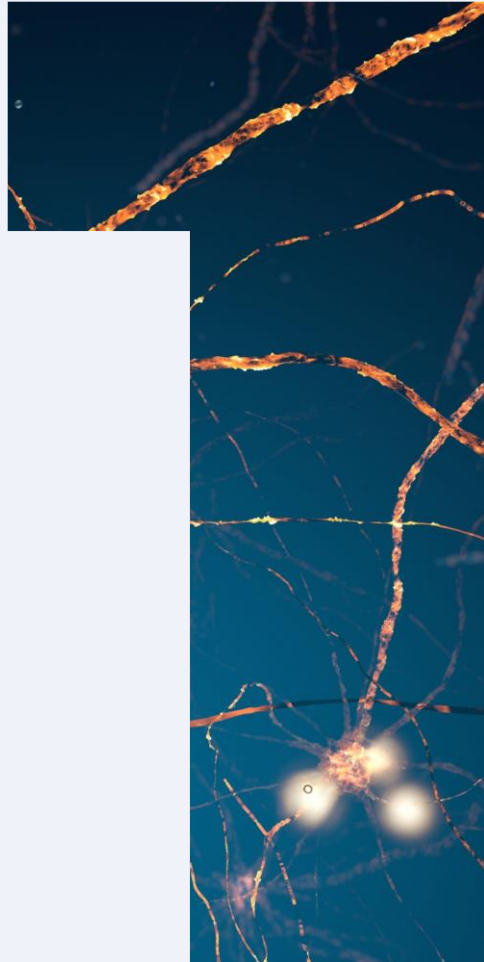
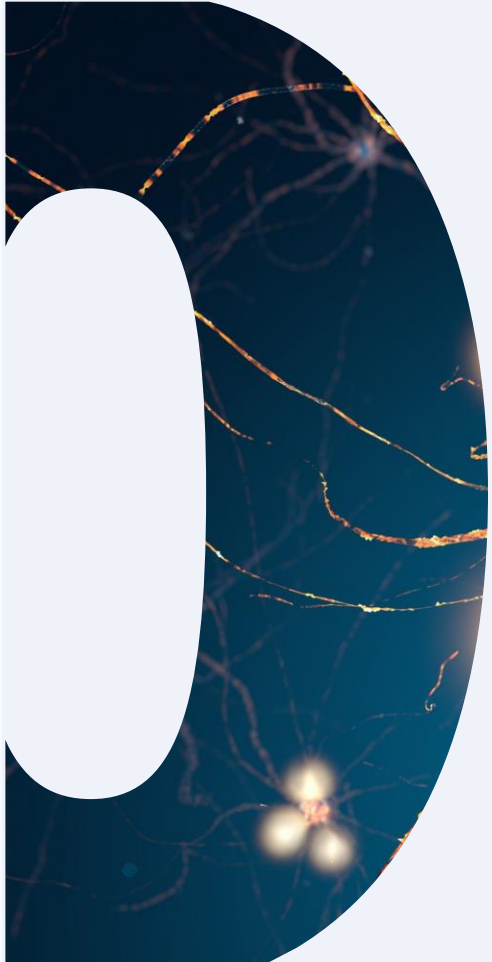
**47%**  
PATIENTS ENROLLED IN PHASE 2<sup>4</sup>

1. Cash balance as @ 30 June 2024

2. Calculated with closing price on @25<sup>th</sup> October 2024 being \$0.75

3. Various ASX Announcements dated 20 January 2023, 22 March 2023, 30 March 2023, 12 September 2023

4. ASX Announcement dated 6<sup>th</sup> September 2024, Positive DSMB Safety Outcome & Phase 2 Trial Progress Update



# **STROKE RECOVERY AND ARG-007**



# SO WHY ARE WE TARGETING STROKE FIRST?

## INCIDENCE



**45 SECONDS**

How often someone suffers an ischaemic stroke in the US<sup>1</sup>

## SOCIETAL IMPLICATIONS



**ONLY 10%**

will recover almost completely, due to the extent of brain cell damage<sup>2</sup>

## THE IMPORTANCE OF TIME



**1.9 MILLION**

brain cells are attacked each minute during a stroke<sup>3</sup>

**FIRST IN CLASS DRUG ADDRESSING \$12B MARKET<sup>4</sup>**

1. US Centers for Disease Control and Prevention (CDC)

2. Stoke Foundation

3. Saver, JL (2006). "Time is Brain". *Stroke*, 37 (1), pp 236-266

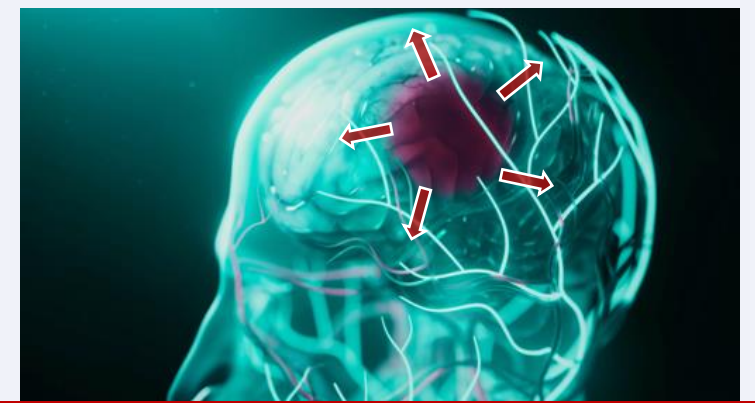
4. Coherent Market Insights Report – Acute Ischemic Stroke (AIS) Market Analysis, Oct 2023



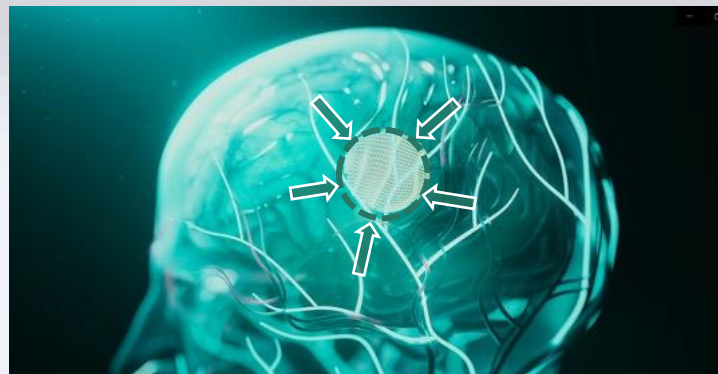
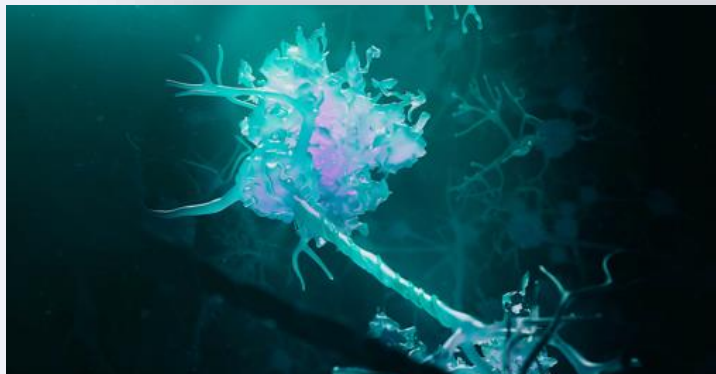
ISCHEMIC STROKE  
EXAMPLE



# HOW ARG-007 WORKS IN STROKE

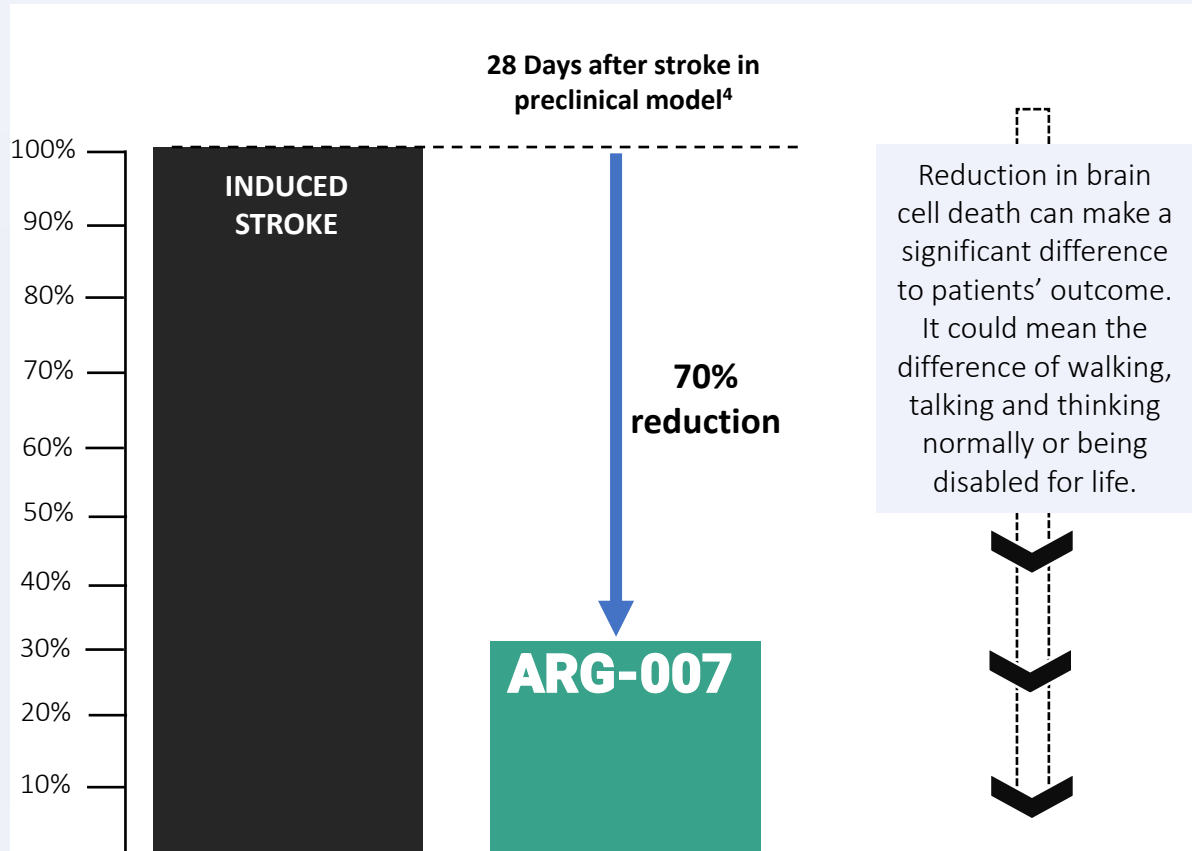


INITIAL INFARCTION SETS OFF A CASCADE OF CELL DEATH THAT **WILL CONTINUE SPREADING FROM LOCATION**



**ARG-007 STOPS THE CASCADE OF CELL DEATH** & PROVIDES A PROTECTION BARRIER AROUND THE INITIAL INFARCTION

# ENCOURAGING STROKE RESULTS TO DATE



This protective effect remained significant (70%), showing a significant reduction in brain tissue death for at least 28 days post stroke following a single i.v. injection of ARG-007

## PRECLINICAL & CLINICAL DATA

**SAFE TO ADMINISTER IN THE FIELD<sup>1</sup>**

**CAN BE ADMINISTERED WITH CLOT DISSOLVING DRUG<sup>2</sup>**

**DOSES OF ARG-007 SAFE & WELL TOLERATED IN HEALTHY HUMAN PHASE 1<sup>3</sup>**

## PHASE 2 IN ISCHAEMIC STROKE PATIENT

*These findings are preliminary in nature. A larger dataset will be required for clinical validation.*

1. Liddle, L. et al (2019). *PLoS one*, 14(11), e0224870.
2. ASX Announcement 'Study shows arg-007 does not degrade when co-administered with ischemic stroke therapeutics' 12 July 2021
3. ASX Announcement 'Final Phase 1 Clinical Trial Report Confirms Argenica Successfully Passes Critical Milestone' 15 May 2023
4. Meloni, B. P. et al (2020) *Neurotherapeutics: the journal of the American Society for Experimental NeuroTherapeutics*, 17(2), 627–634



# PHASE 2 STROKE TRIAL



# PHASE 2 TRIAL DESIGN IN ACUTE ISCHAEMIC STROKE

PATIENT HAS A STROKE



PATIENT IN AMBULANCE



ARRIVES AT HOSPITAL



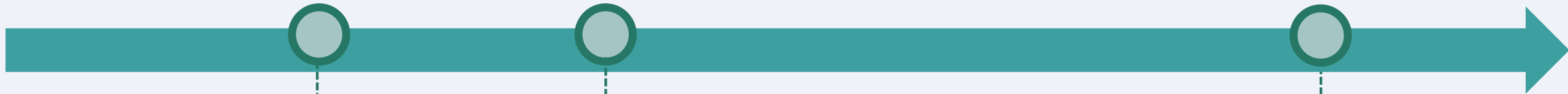
DIAGNOSE STROKE TYPE



THROMBECTOMY



REHAB BEGINS



- Initial screening of patients to meet inclusion criteria
- Consent for thrombectomy & ARG-007 trial

- Administration of **0.3mg/kg ARG-007** or saline placebo
- All patients receive thrombectomy

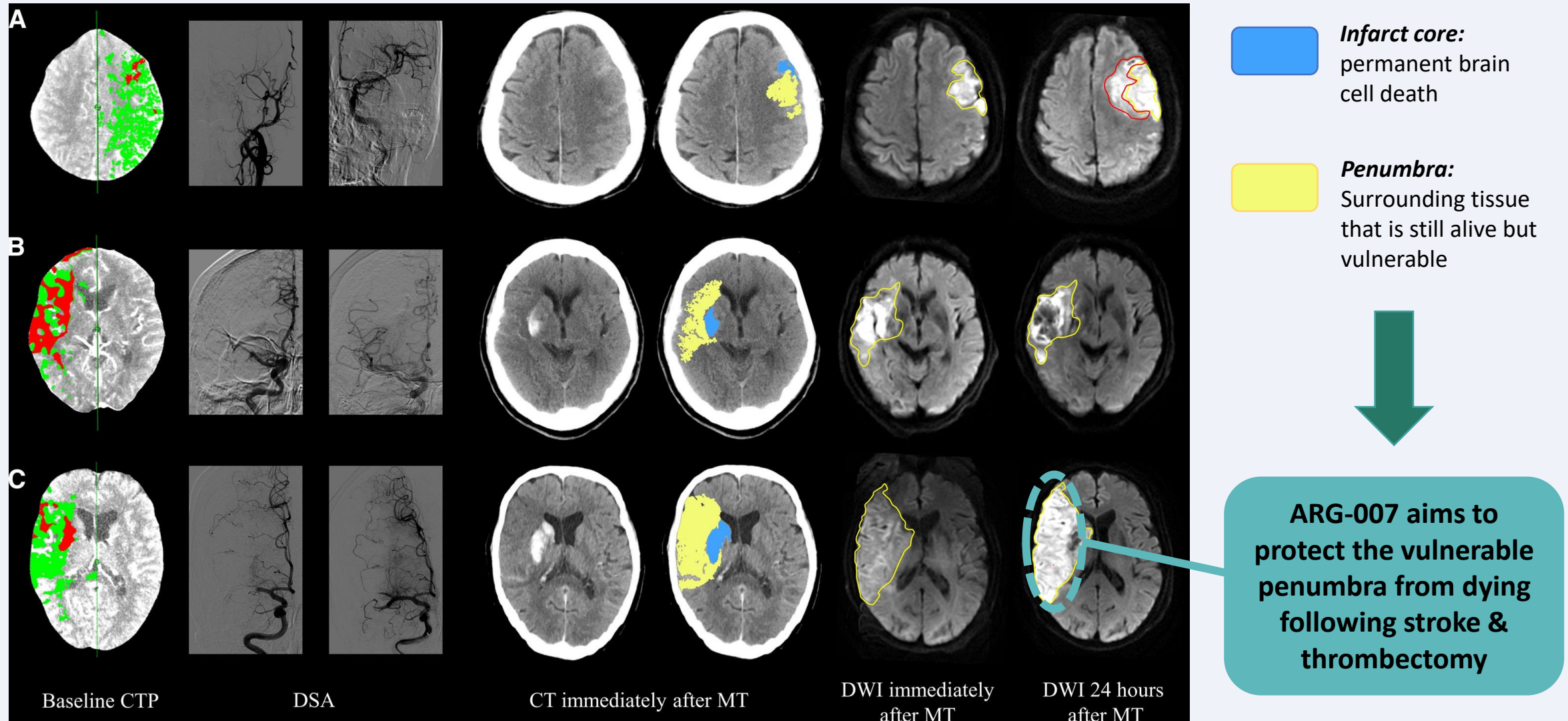
### Endpoints

- Mortality rate and frequency of **Adverse and Serious Adverse Events**; timepoints of Day 1, Day 2, Day 3, Day 6 or Discharge, Day 30 and Day 90
- Infarct volume reduction** between ARG-007 and placebo at 48 hours (Day 3 ± 1 day)

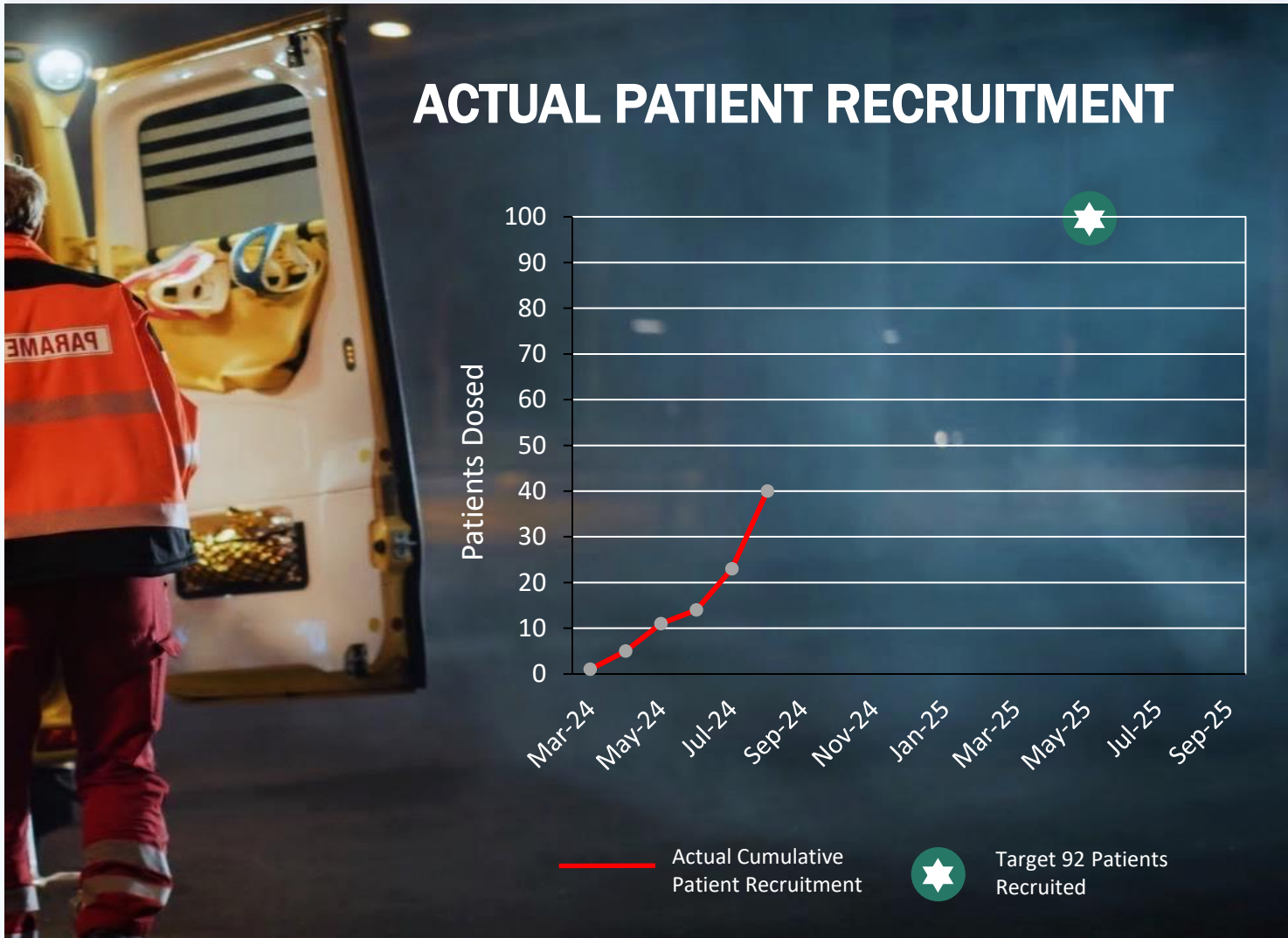


# EXAMPLE OF WHAT PHASE 2 TRIAL HOPES TO ACHIEVE:

## PROTECTING VULNERABLE BRAIN TISSUE (PENUMBRA) FOLLOWING STROKE & THROMBECTOMY



# PHASE 2 CLINICAL TRIAL IN STROKE

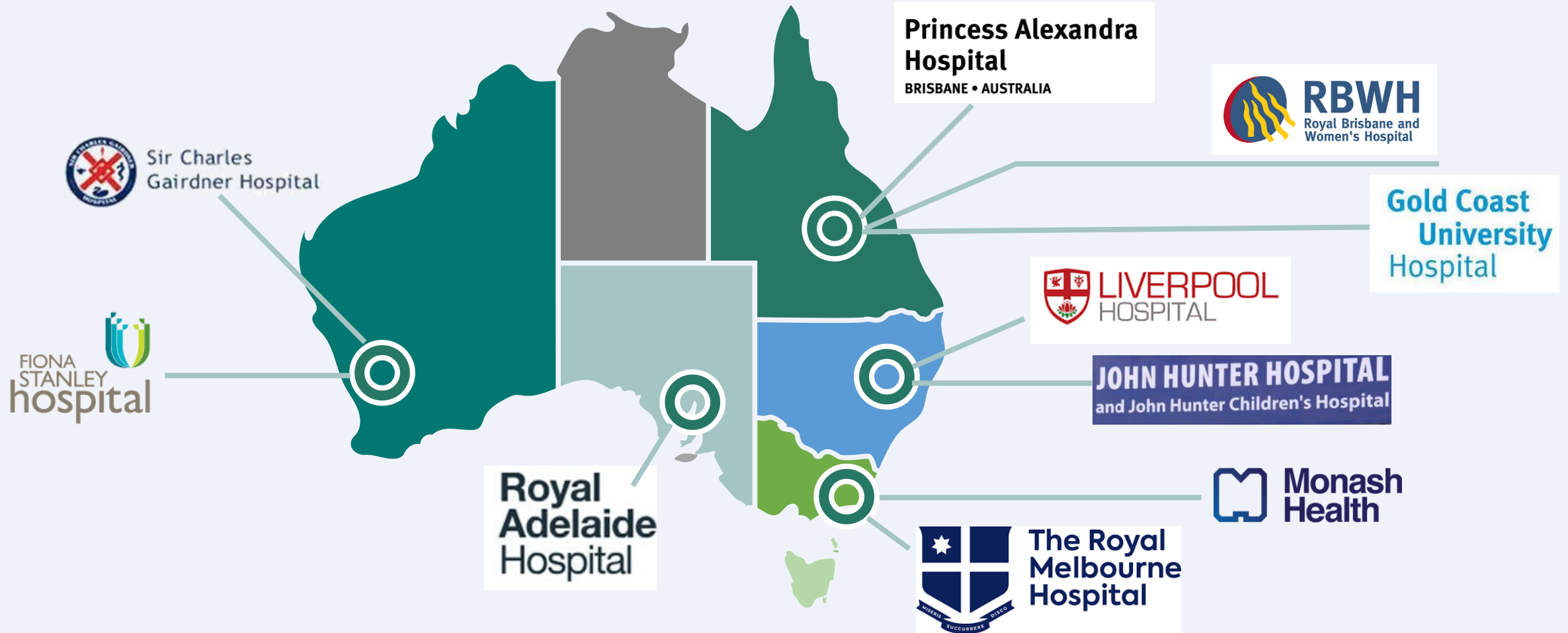


- 10 Australian hospitals activated to recruit 92 patients, currently 47% patients dosed<sup>1</sup>.
- Double-blinded, randomised, placebo-controlled study with 0.3mg/kg dose of ARG-007.
- ARG-007 given to patients that have suffered a diagnosed acute ischemic stroke eligible for thrombectomy.
- Objectives;
  1. Safety
  2. Tolerability
  3. Pharmacokinetics
  4. Preliminary Efficacy
- Data Safety Monitoring Board confirmed trial safe to continue after first 23 patients.



# PHASE 2 ENROLMENT

92 participants being enrolled across 10 stroke centres in Australia:







# **THE OPPORTUNITY FOR ARG-007 IN OTHER INDICATIONS**

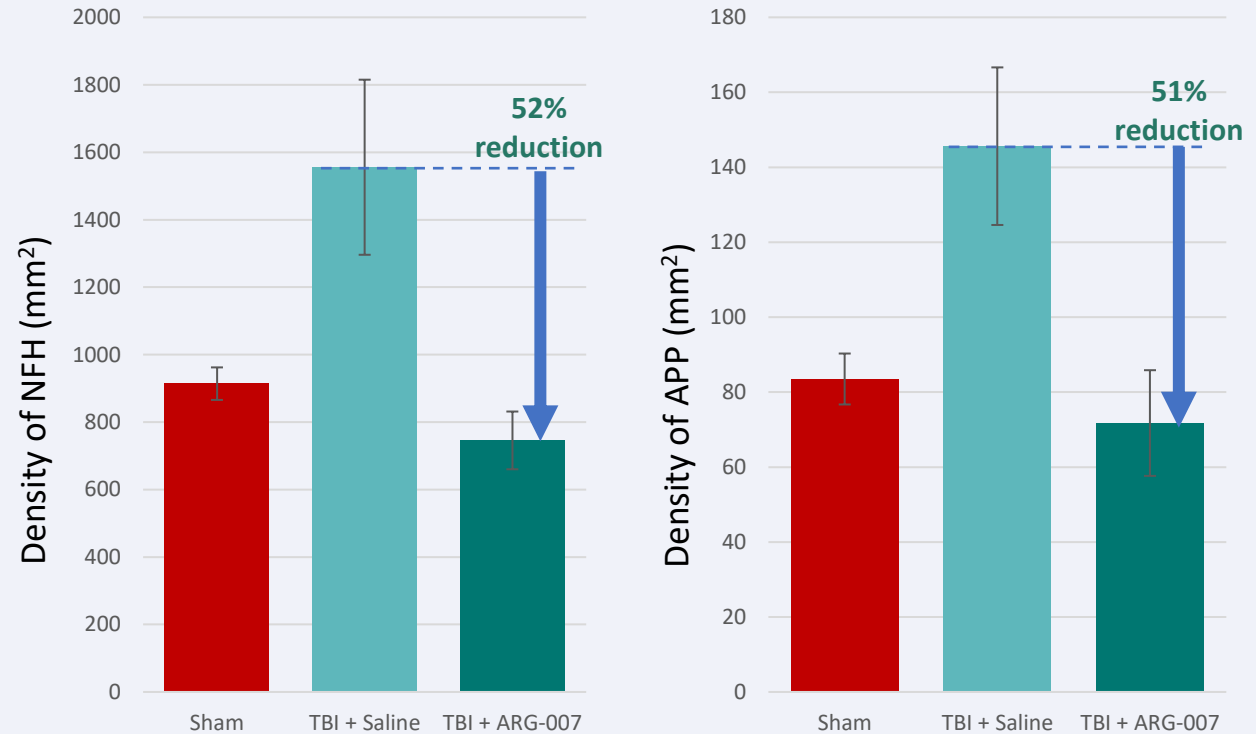


# ARG-007 POTENTIAL IN TBI – RAT DATA



- Estimated **USD\$18.6bn** market size by 2031<sup>1</sup>
- ARG-007 has shown efficacy in pre-clinical studies<sup>2</sup>
- Awarded **A\$1.2m** grant to advance pre-clinical studies<sup>3</sup>

## ARG-007 SIGNIFICANTLY REDUCES NFH PROTEIN AND APP FOLLOWING TBI<sup>2</sup>



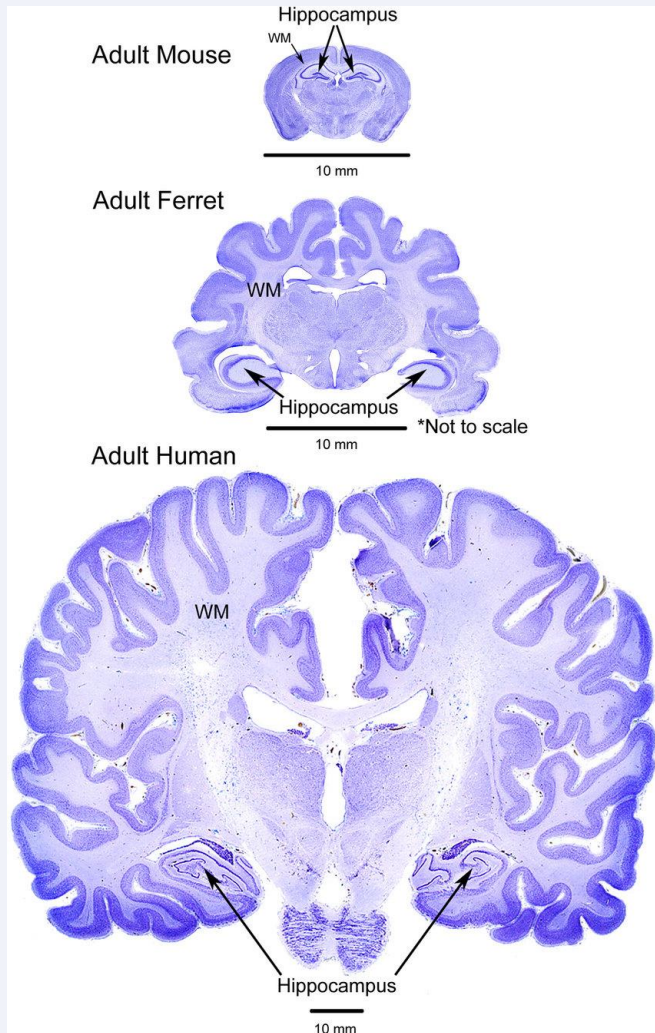
ARG-007 was found to protect brain cells in the injured brain by significantly reducing the accumulation of proteins that contribute to brain cell injury and death following TBI, specifically neurofilament heavy protein (NFH) and amyloid precursor protein (APP).

1. Traumatic brain injuries assessment market research, 2031 – Allied Market Research

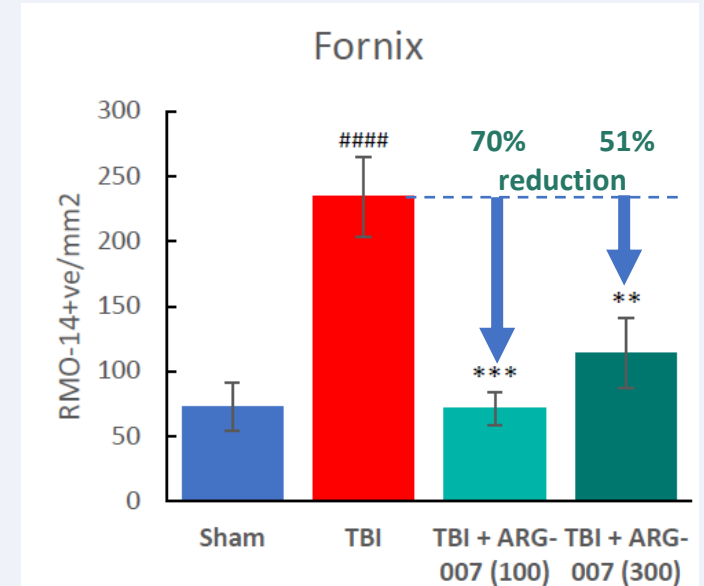
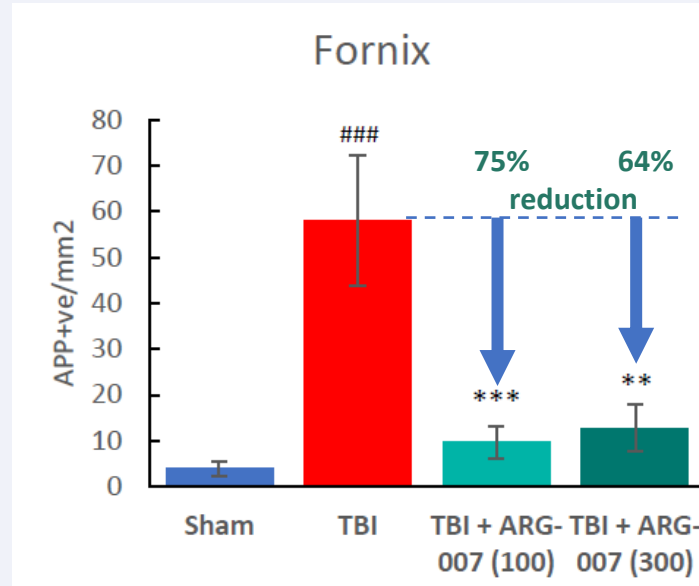
2. ASX Announcement titled 'ARG-007 protects brain cells in moderate traumatic brain injury model' 22 June 2023

3. ASX Announcement titled 'Argenica awarded \$1.2m grant for Traumatic brain injury project under the CRC-P program' dated 20 Jan 2023

# ARG-007 POTENTIAL IN TBI – FERRET DATA



## ARG-007 SIGNIFICANTLY REDUCES AMYLOID PRECURSOR PROTEIN (APP) AND NEUROFILAMENT M-14.9 (RMO-14) & FOLLOWING TBI<sup>1</sup>



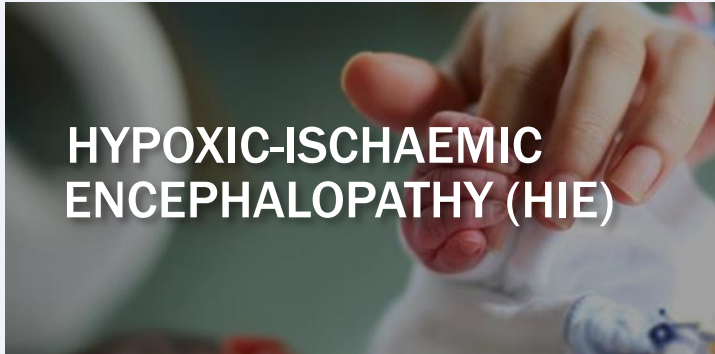
ARG-007 was found to protect brain cells in the injured brain by significantly reducing the accumulation of proteins associated with injury in brain cell following TBI, specifically APP and RMO-14. ### TBI injury is significantly difference from sham, confirming injury impairment. \*\*\*p<0.001, \*\*p<0.01 \*p<0.05 statistically significant difference of TBI:Vehicle to TBI:ARG007 treated animals to confirm therapeutic response of ARG-007.

Image reference – Schwerin et al 2017, Establishing the ferret as a gyrencephalic animal model of traumatic brain injury: Optimization of controlled cortical impact procedures, Journal of Neuroscience Methods

1. ASX Announcement dated 15 May 2024, ARG-007 Significantly Reduces Effects of Traumatic Brain Injury in Preclinical Study



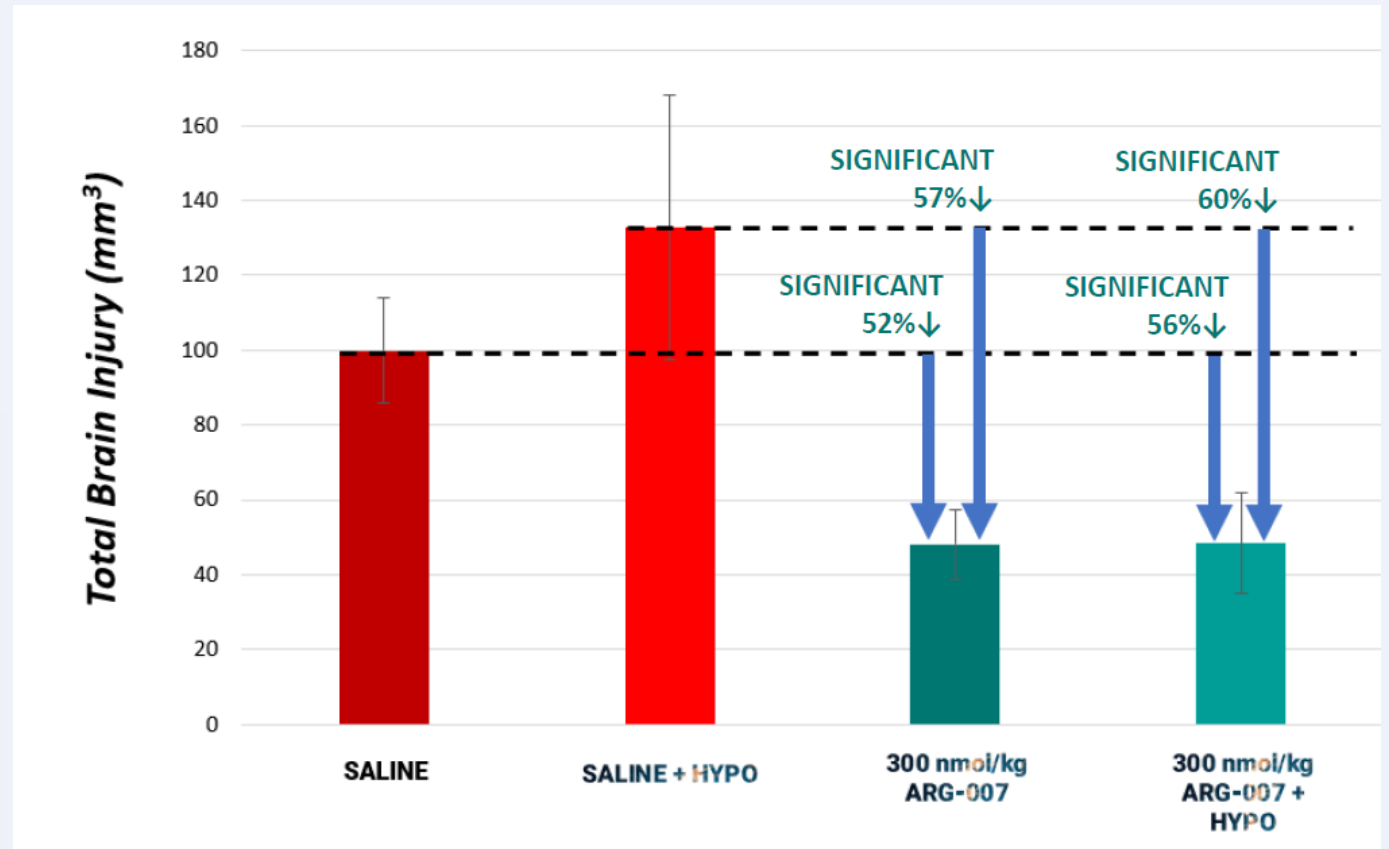
# ARG-007 POTENTIAL IN HIE



**HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE)**

- HIE occurs in 1.5 to 2.5 births per 1000<sup>1</sup>
- Current standard of care is hypothermia
- Awarded **A\$2.5m** grant to advance pre-clinical studies<sup>2</sup>

## TOTAL BRAIN INJURY AT 4 WEEK POST HIE WITH ARG-007 TREATMENT OR ARG-007 WITH STANDARD OF CARE HYPOTHERMIA<sup>3</sup>



1. Hypoxic Ischemic Encephalopathy: Pathophysiology and Experimental Treatments Kimberly A. Allen, MSN, RN and Debra H. Brandon, PhD, RN, CCNS, FAAN  
 2. ASX Announcement titled 'Significant non-dilutive funding to Complete preclinical hypoxic ischaemic Encephalopathy studies' dated 30 March 2023  
 3. ASX Announcement titled 'ARG-007 is an effective stand-alone therapy in preclinical study of term hypoxic ischaemic encephalopathy' dated 18 October 2023



# FDA HAS GRANTED ODD & RPDD STATUS FOR HIE<sup>1</sup>

Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) status to ARG-007 for the treatment of Hypoxic Ischaemic Encephalopathy (HIE).

- ODD qualifies AGN for incentives including:
  - Tax credits for qualified clinical trials
  - Exemption from user fees
  - Potential seven years of market exclusivity after approval
- Granting of Orphan Drug Designation for ARG-007 in HIE forms a key pillar of Argenica's commercialisation strategy
- The potential for extensive market exclusivity following approval of ARG-007 is an extremely compelling commercial driver for the Company
- RPDD voucher can be used to obtain priority review for a subsequent human drug application, this voucher can also be sold. Only given on drug approval.





# NEAR-TERM CATALYSTS



## Each Quarter

- Phase 2 Trial Updates



## Q4 CY24

- Investigational New Drug Application to be submitted to the FDA



## Q2-Q4 CY25

- Phase 2 Dosing Complete
- Release of Phase 2 Top Line Data



## Q3 CY24 – Q4 CY25

- Preclinical data for indications outside of stroke



# INVESTMENT HIGHLIGHTS

## 1# SOLVING LARGE UNMET NEEDS

Nervous system disorders are the biggest cause of poor health globally<sup>1</sup>. Currently there are no marketed safe, early intervention therapeutics capable of protecting the brain from damage following stroke<sup>2</sup>. Argenica is one of the furthest progressed clinical drug development companies globally focused on this indication.

## 2# SIGNIFICANT PRE-CLINICAL DATA

ARG-007 (R18D) has amassed a huge amount of preclinical data scientifically validating the efficacy, safety and mechanism of action of the drug. There are over 25 peer reviewed publication, as well as the Phase 1 clinical trial data, derisking ARG-007.

## 3# NEAR-TERM CATALYSTS

Several clinical and preclinical data points will be generated over the next 12 months, providing significant upside to investors.

## 4# PARTNERING OPPORTUNITIES

Given the focus on neurology assets and blockbuster indications by pharmaceutical companies, Argenica is well positioned to partner post Phase 2.



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