



AGM PRESENTATION ASX: AGN

MANAGING DIRECTOR PRESENTATION
NOVEMBER 2024



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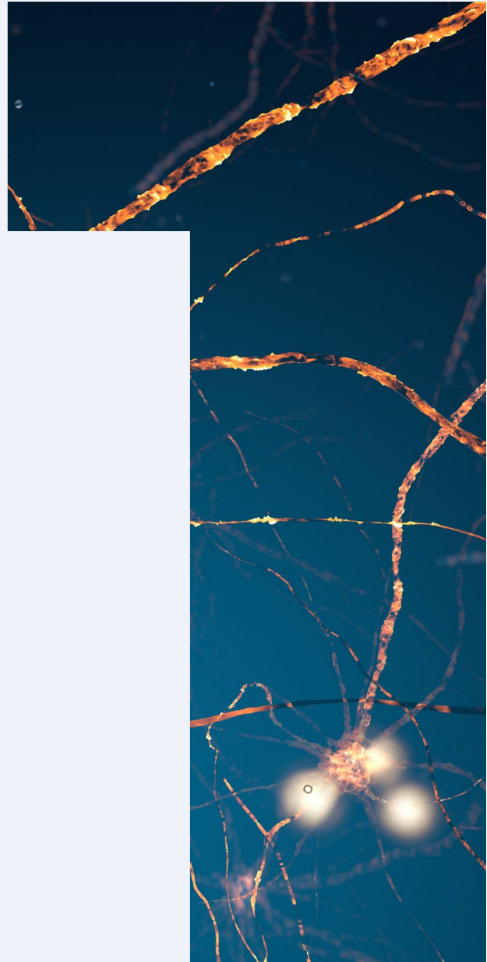
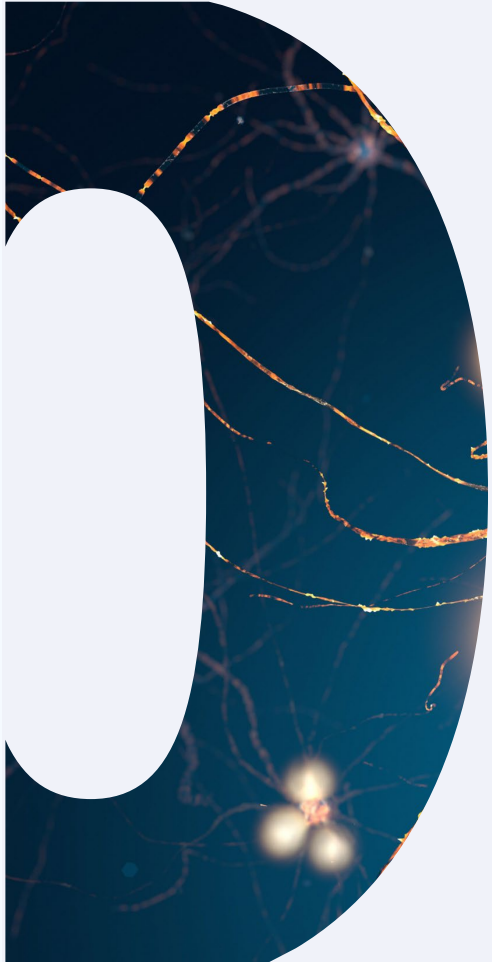
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NEUROPROTECTION THE THERAPEUTIC OPPORTUNITY



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 by reducing brain injury



IMPACT

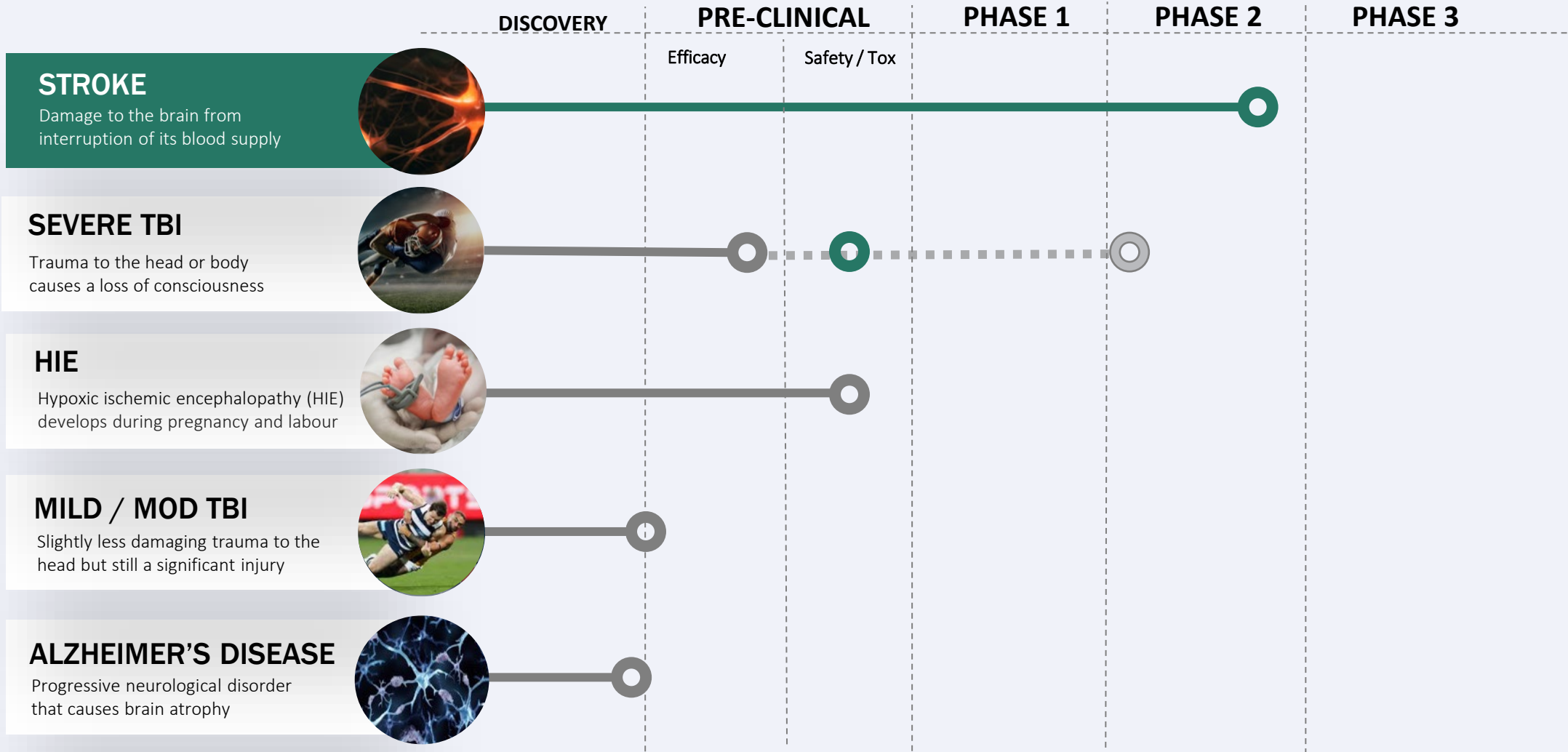
Create positive, life-altering impact for millions suffering from neurological conditions, offering new hope


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 2030¹

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

USD\$18.6bn
by 2031²

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

USD\$1.9bn
by 2030³

3. Data Bridge Market Research Market Analysis Study 2023

USD\$13.0bn
by 2031⁴

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

Meloni, B. P. et al (2020) *Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics*, 17(2), 627–634

70% reduction
in Brain Tissue Death 28 Days after stroke

52% reduction
in neurofilament heavy protein

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

51% reduction
in amyloid precursor protein

52% reduction
in total brain injury 4 weeks after injury

ASX Announcement titled 'ARG-007 is an effective stand-alone therapy in preclinical study of term hypoxic ischaemic encephalopathy' dated 18 October 2023

60% reduction
compared to hypothermia

65% reduction
in Abeta aggregation

ASX Announcements dated 9th February 2023, 1st August 2023 and 3 November 2023

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

\$13.9M
CASH @ BANK¹

\$93.5M
MARKET CAP²

+\$4M
NON-DILUTIVE GRANTS³

128.1M
SHARES ON ISSUE

37%
SHARES HELD BY TOP 20

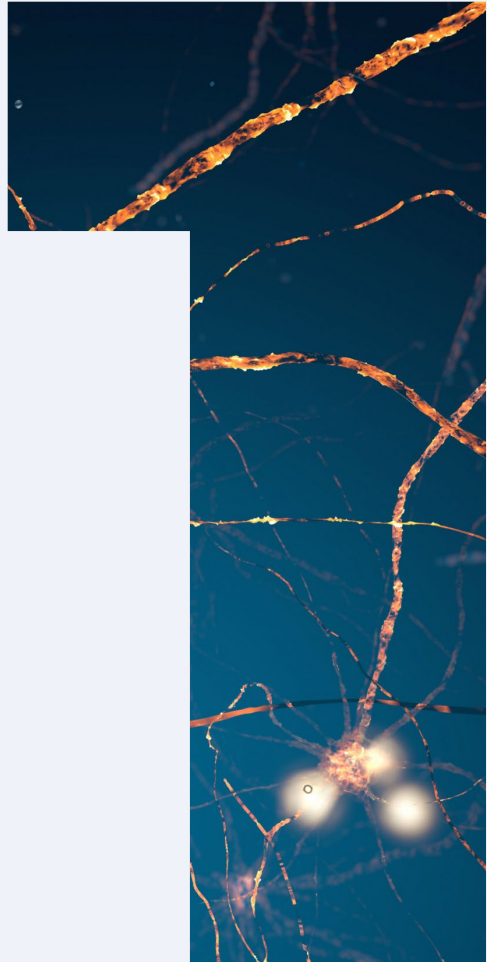
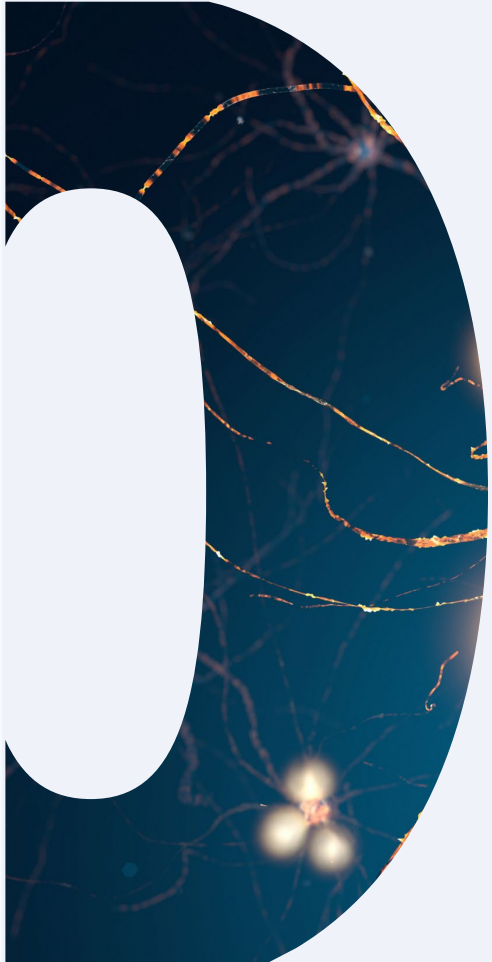
63%
PATIENTS ENROLLED IN PHASE 2⁴

1. Cash balance as @ 30 September 2024

2. Calculated with closing price on @25th 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 6th September 2024, Positive DSMB Safety Outcome & Phase 2 Trial Progress Update



PHASE 2 STROKE TRIAL

SO WHY ARE WE TARGETING STROKE FIRST?

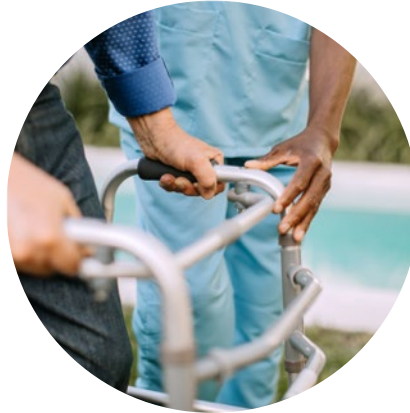
INCIDENCE



45 SECONDS

How often someone suffers an ischaemic stroke in the US¹

SOCIETAL IMPLICATIONS



ONLY 10%

will recover almost completely, due to the extent of brain cell damage²

THE IMPORTANCE OF TIME



1.9 MILLION

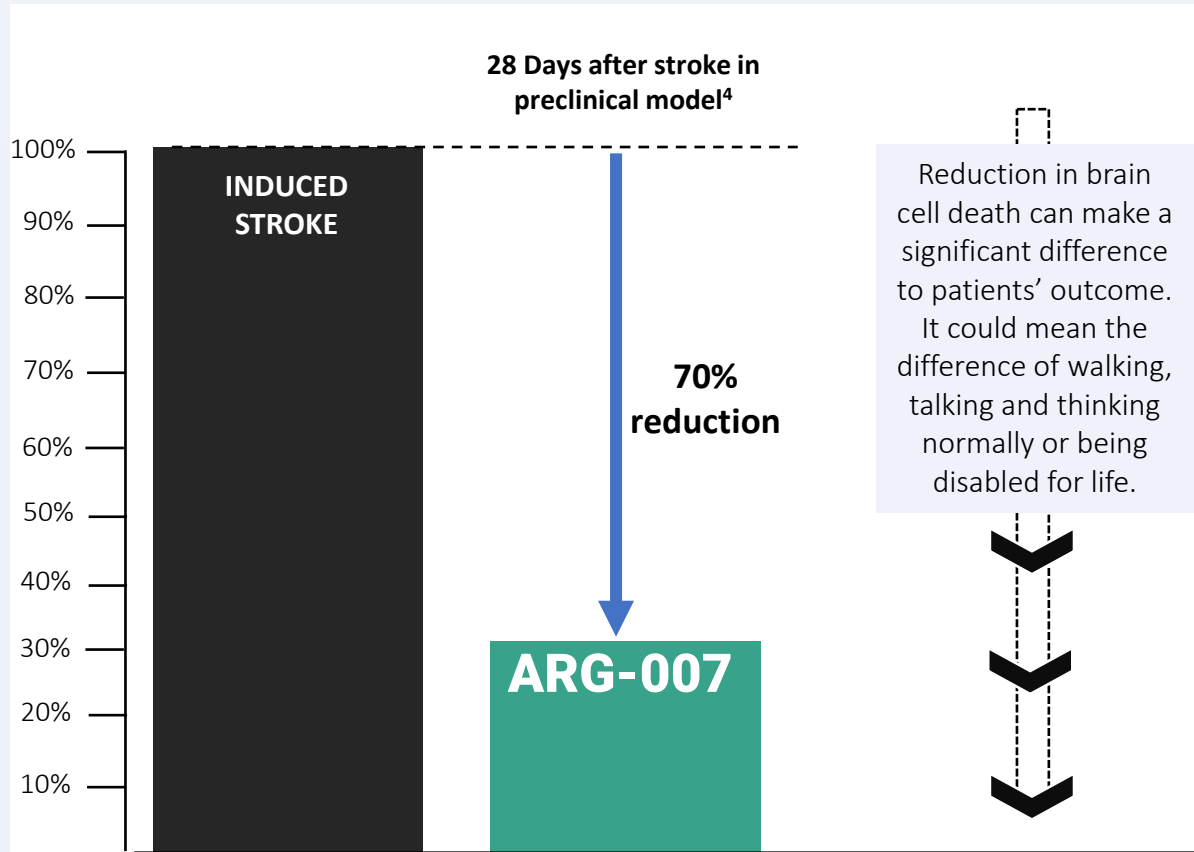
brain cells are attacked each minute during a stroke³

FIRST IN CLASS DRUG ADDRESSING \$12B MARKET⁴

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



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 FIELD¹

CAN BE ADMINISTERED WITH CLOT DISSOLVING DRUG²

DOSES OF ARG-007 SAFE & WELL TOLERATED IN HEALTHY HUMAN PHASE 1³

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



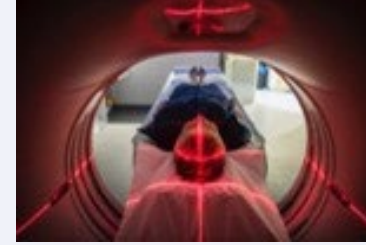
PATIENT IN AMBULANCE



ARRIVES AT HOSPITAL



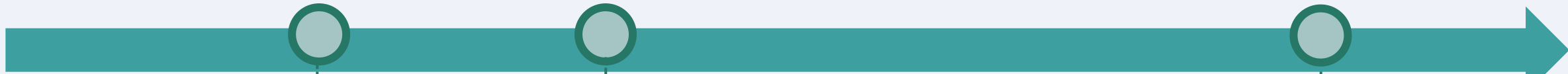
DIAGNOSE STROKE TYPE



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

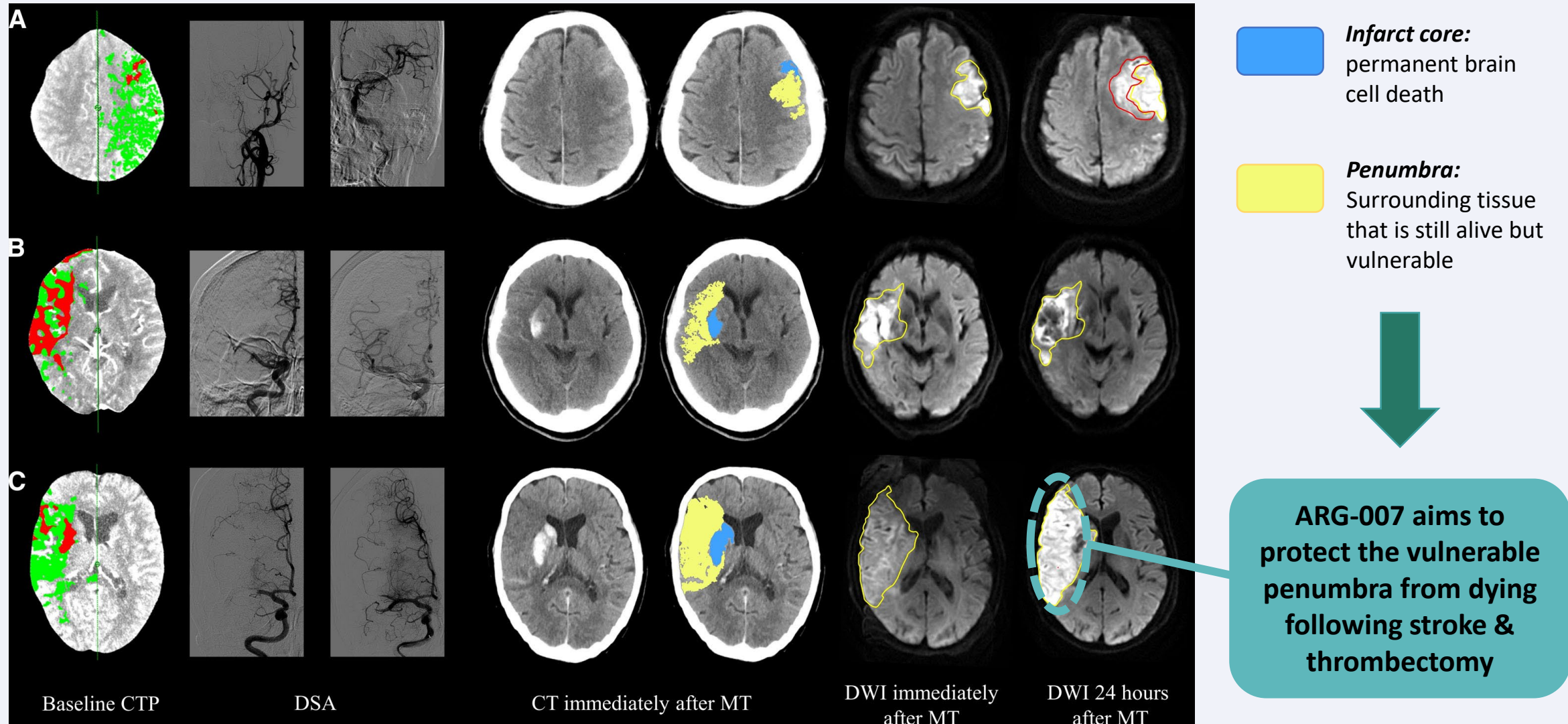
Endpoints

- 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)

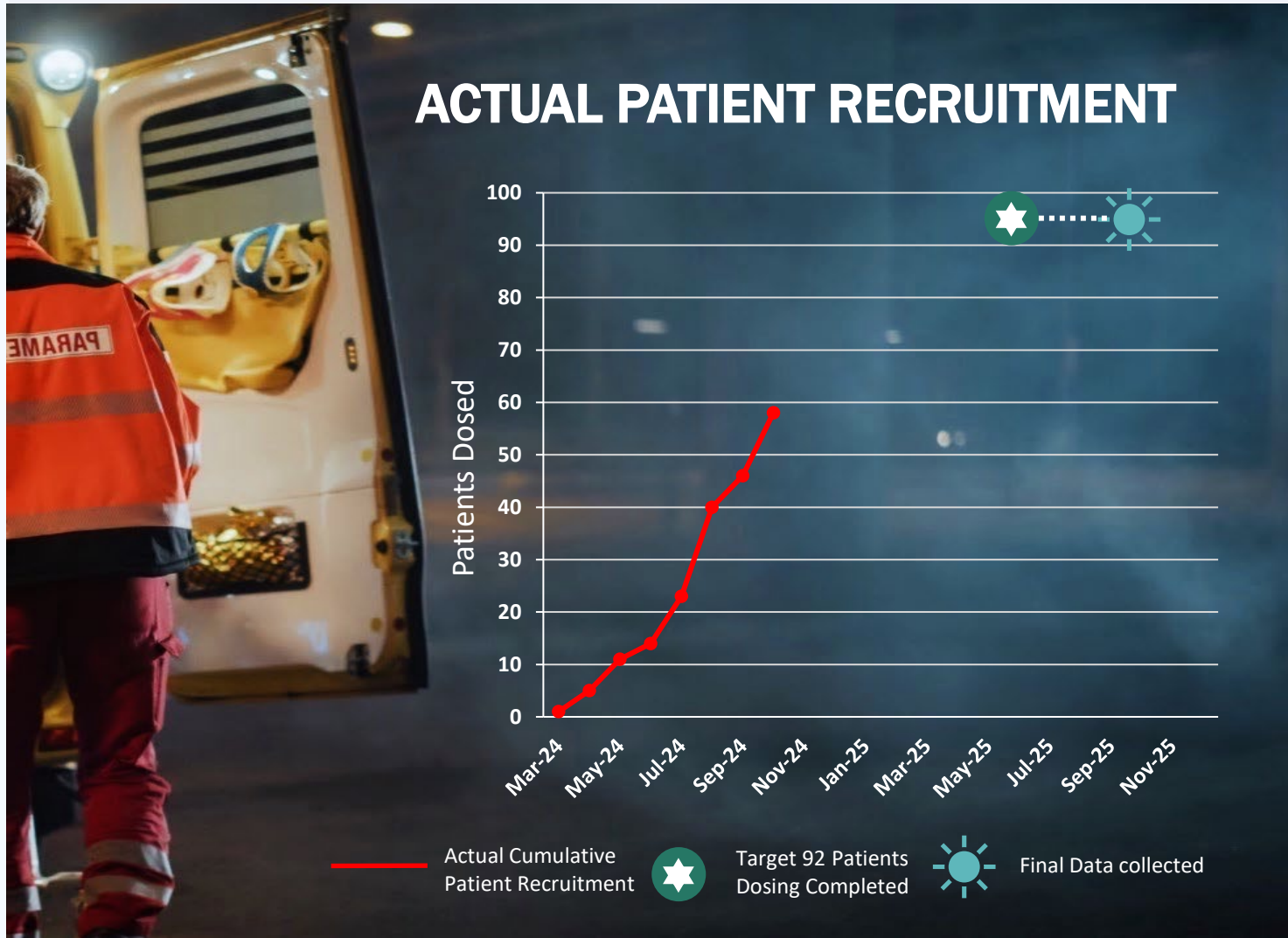


EXAMPLE OF WHAT PHASE 2 TRIAL HOPES TO ACHIEVE:

PROTECTING VULNERABLE BRAIN TISSUE (PENUMBRA) FOLLOWING STROKE & THROMBECTOMY



PHASE 2 CLINICAL TRIAL IN STROKE

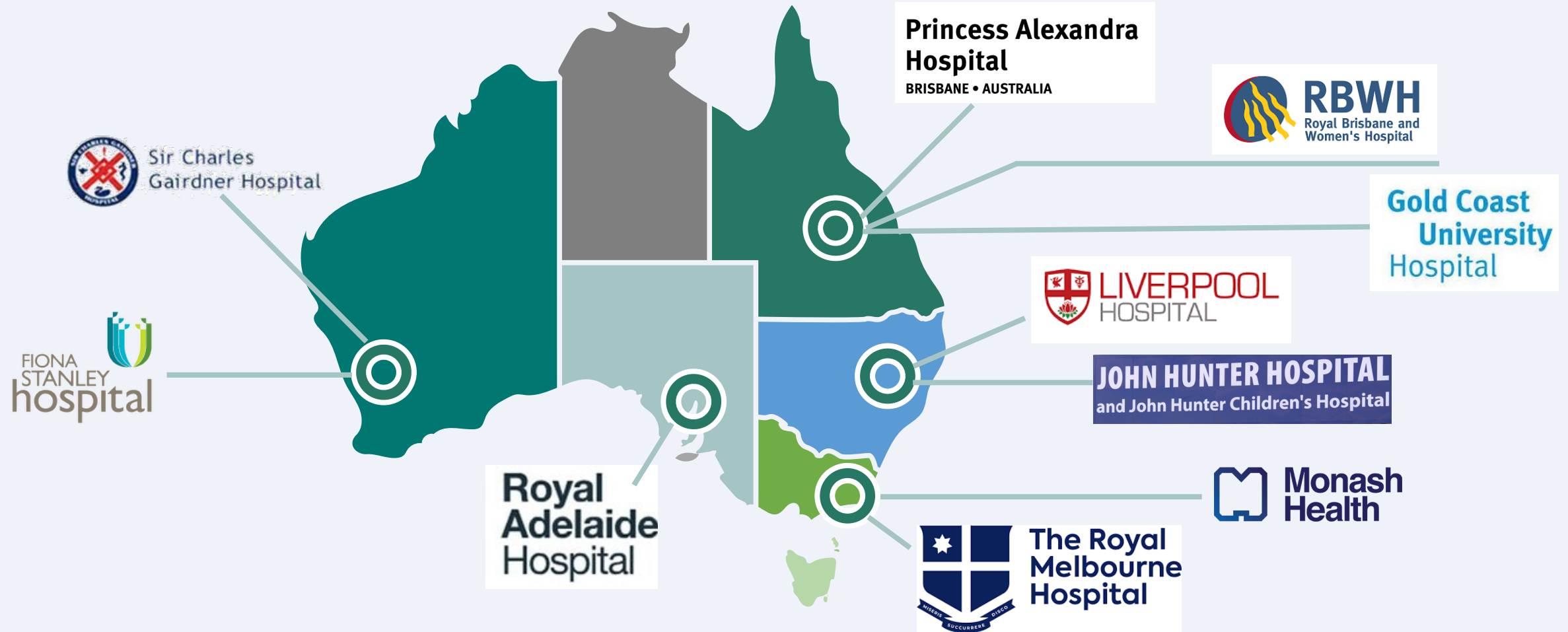


- 10 Australian hospitals activated to recruit 92 patients, currently 63% patients dosed¹.
- Double-blinded, randomised, placebo-controlled study with 0.3mg/kg dose of ARG-007.
- ARG-007 given to patients that have suffered a diagnosed acute ischemic stroke eligible for thrombectomy.
- Objectives;
 1. Safety
 2. Tolerability
 3. Pharmacokinetics
 4. Preliminary Efficacy
- Data Safety Monitoring Board confirmed trial safe to continue after 46 (50%) patients dosed.



PHASE 2 ENROLMENT

92 participants being enrolled across 10 stroke centres in Australia:





THE OPPORTUNITY FOR ARG-007 IN OTHER INDICATIONS

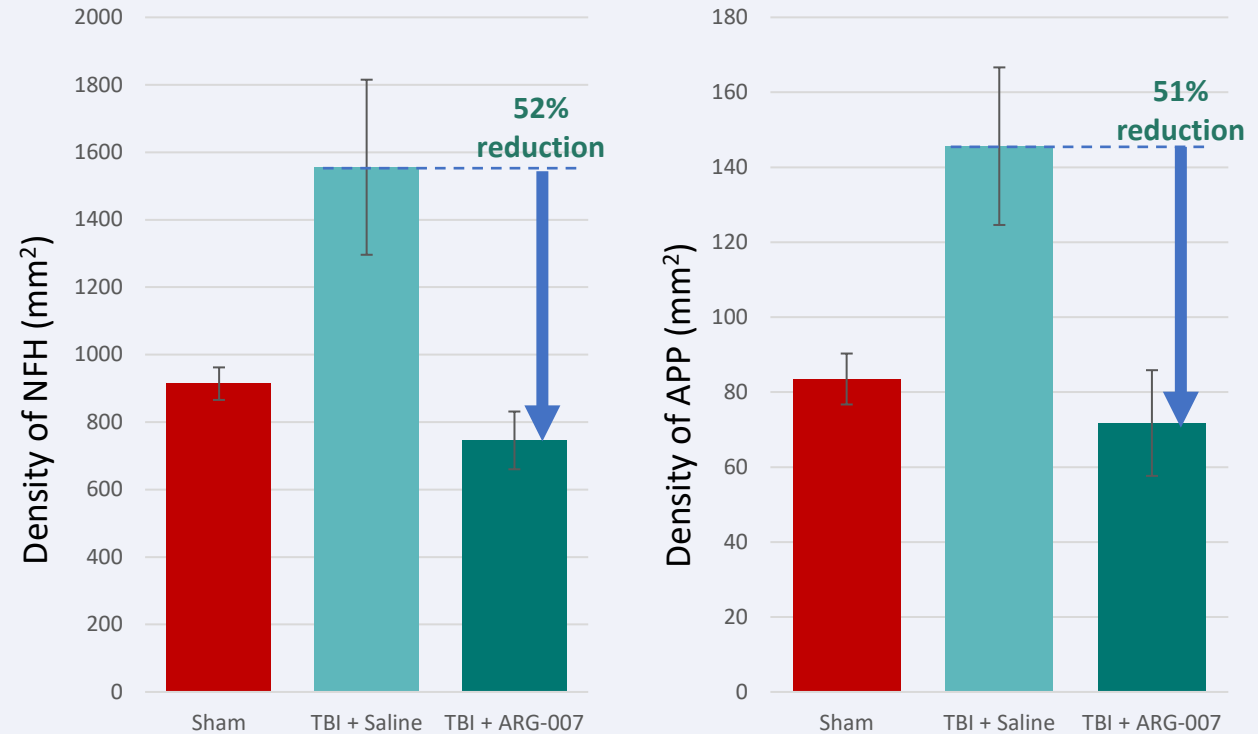


ARG-007 POTENTIAL IN TBI – RAT DATA



- Estimated **USD\$18.6bn** market size by 2031¹
- ARG-007 has shown efficacy in pre-clinical studies²
- Awarded **A\$1.2m** grant to advance pre-clinical studies³

ARG-007 SIGNIFICANTLY REDUCES NFH PROTEIN AND APP FOLLOWING TBI²



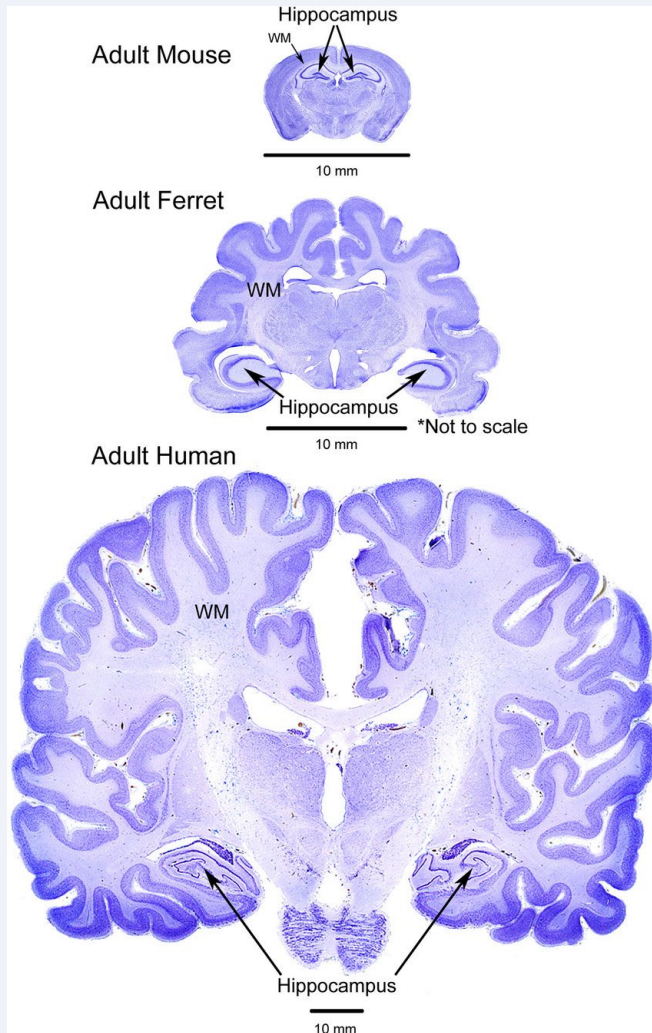
ARG-007 was found to protect brain cells in the injured brain by significantly reducing the accumulation of proteins that contribute to brain cell injury and death following TBI, specifically neurofilament heavy protein (NFH) and amyloid precursor protein (APP).

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

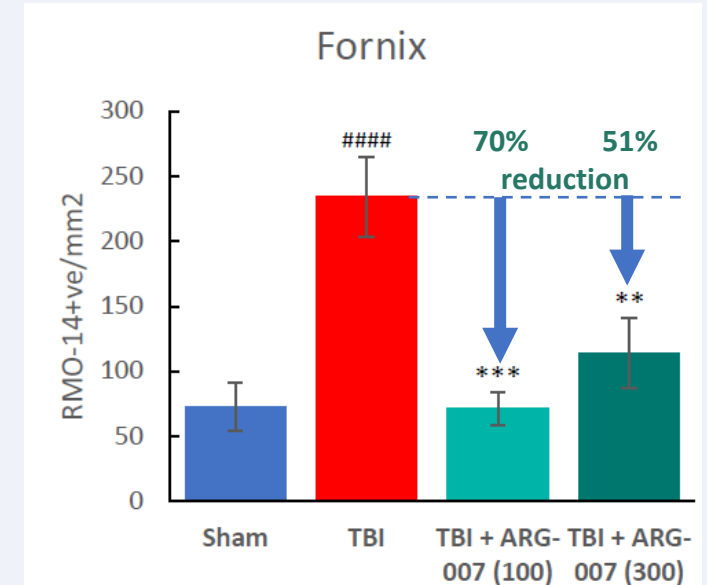
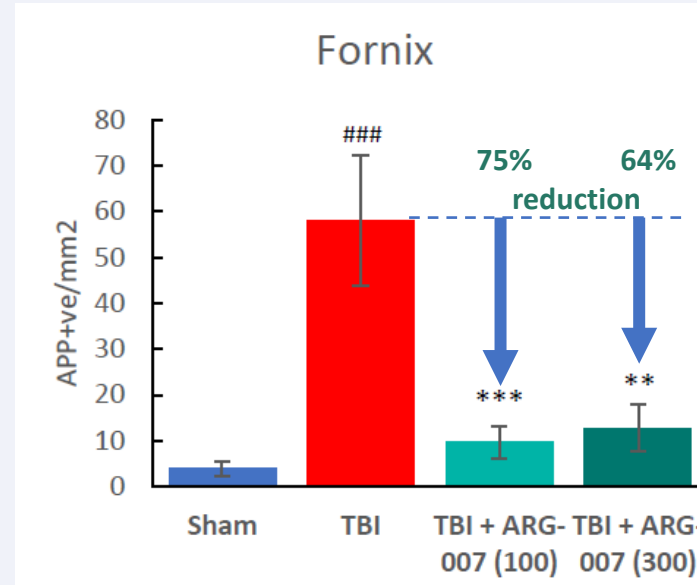
2. ASX Announcement titled 'ARG-007 protects brain cells in moderate traumatic brain injury model' 22 June 2023

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 TBI¹



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

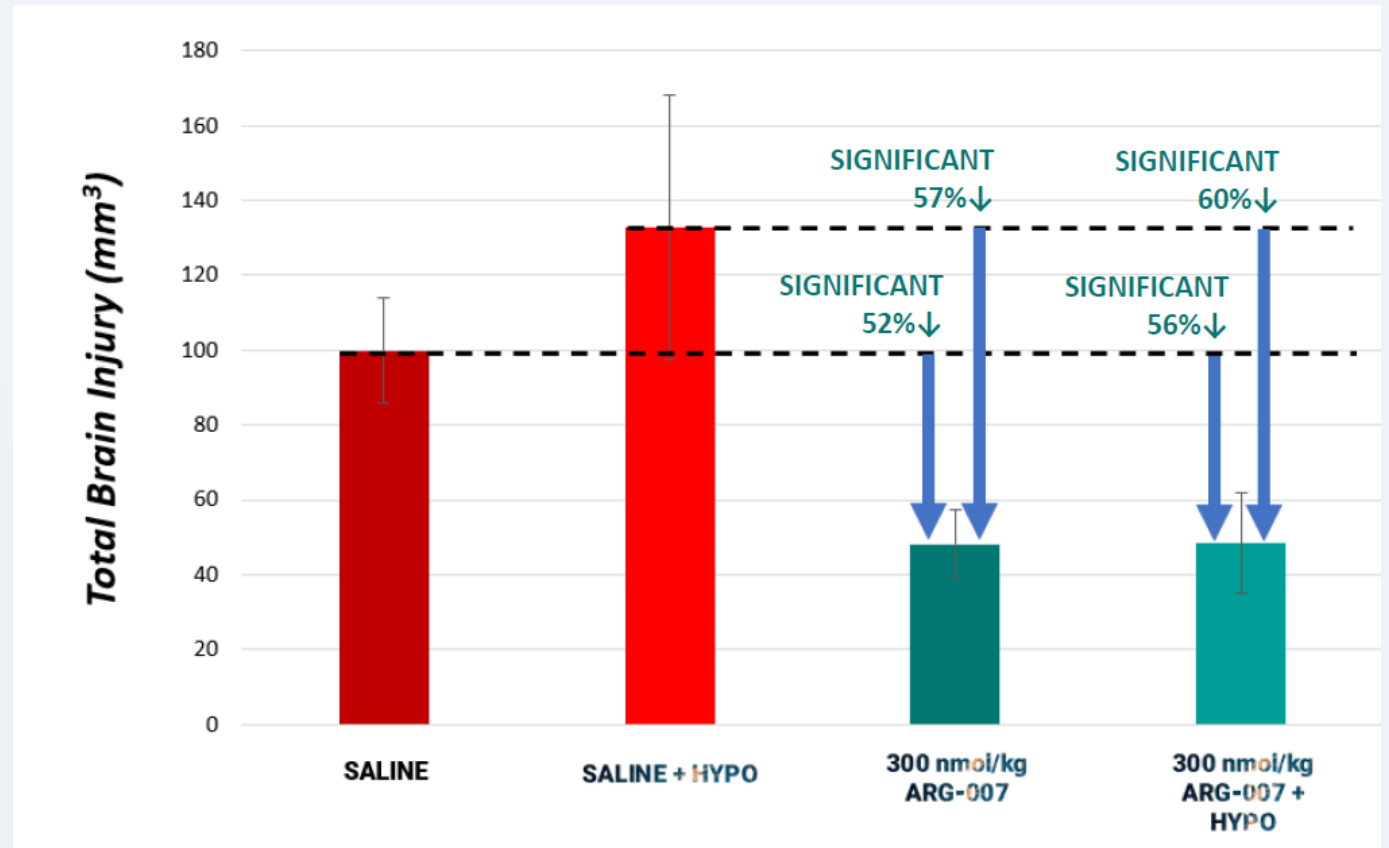


ARG-007 POTENTIAL IN HIE

HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE)

- HIE occurs in 1.5 to 2.5 births per 1000¹
- Current standard of care is hypothermia
- Awarded **A\$2.5m** grant to advance pre-clinical studies²

TOTAL BRAIN INJURY AT 4 WEEK POST HIE WITH ARG-007 TREATMENT OR ARG-007 WITH STANDARD OF CARE HYPOTHERMIA³



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 HIE¹

Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation status to ARG-007 and ARG-006 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 in HIE forms a key pillar of Argenica's commercialisation strategy
- The potential for extensive market exclusivity following approval 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 globally¹. Currently there are no marketed safe, early intervention therapeutics capable of protecting the brain from damage following stroke². 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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