argenica
THERAPEUTICS

INVESTOR PRESENTATION
ASX: AGN

MANAGING DIRECTOR PRESENTATION
MAY 2025

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NEUROPROTECTION
THE THERAPEUTIC OPPORTUNITY

BREAKTHROUGH
NEUROPROTECTIVE THERAPY

MISSION

Commercialise neuroprotective treatments 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

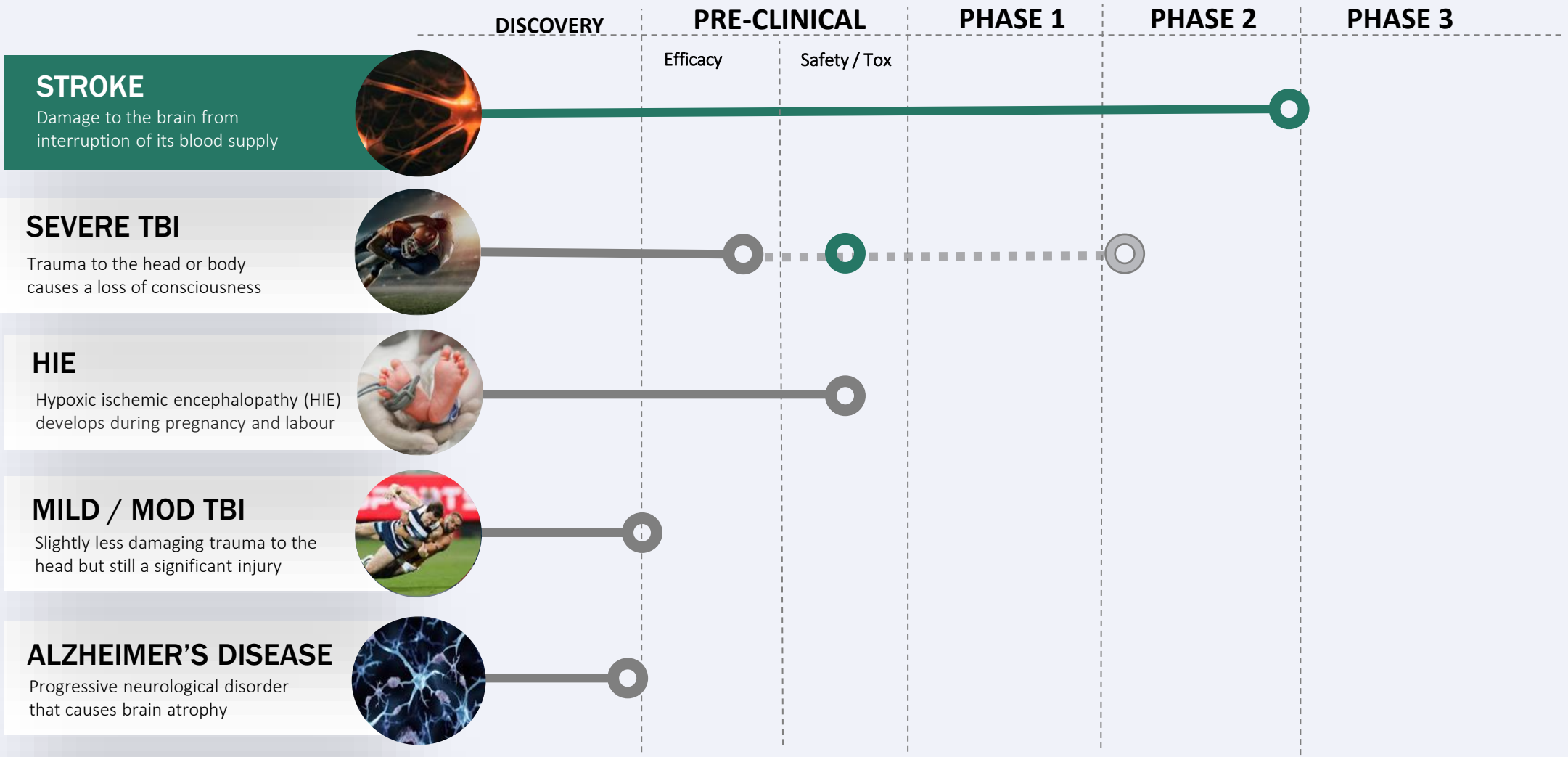
IMPACT

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

ABOUT ARG-007

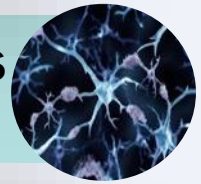
- Cationic poly-arginine peptide
- Multiple mechanisms of action working across multiple conditions
- Granted patents & strong IP
- Significant pre-clinical efficacy
- 25+ peer reviewed papers
- Proven safe for healthy humans

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

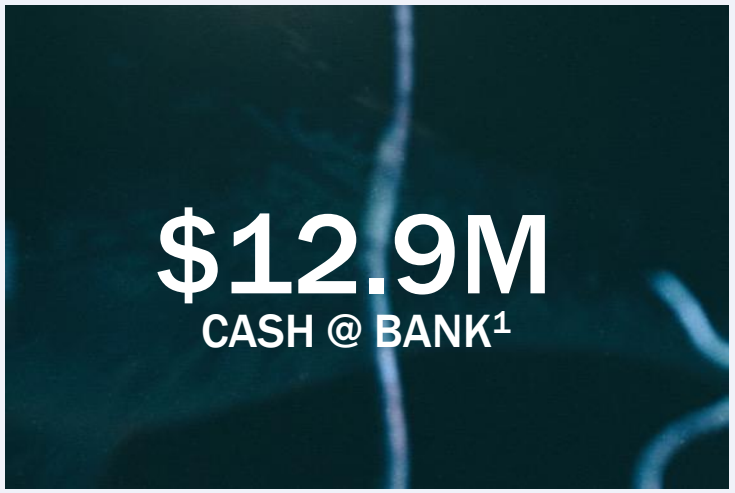
MAIN INDICATIONS	ADDRESSABLE MARKET	SUMMARY OF RESULTS TO DATE
STROKE 	**USD$12bn** by 2030[1]	**66% reduction** in Brain Tissue Death 24 hours after stroke **70% reduction** in Brain Tissue Death 28 Days after stroke
	1. Coherent Market Insights Report – Acute Ischemic Stroke (AIS) Market Analysis, Oct 2023	Meloni, B. P. et al (2020) *Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics*, *17*(2), 627–634
TBI 	**USD$18.6bn** by 2031[2]	**52% reduction** in neurofilament heavy protein **51% reduction** in amyloid precursor protein
	2. Traumatic brain injuries assessment market research, 2031 – Allied Market Research	*ASX Announcement titled 'ARG-007 protects brain cells in moderate traumatic brain injury model' 22 June 2023*
HIE 	**USD$1.9bn** by 2030[3]	**52% reduction** in total brain injury 4 weeks after injury **60% reduction** compared to hypothermia
	3. Data Bridge Market Research Market Analysis Study 2023	*ASX Announcement titled 'ARG-007 is an effective stand-alone therapy in preclinical study of term hypoxic ischaemic encephalopathy' dated 18 October 2023*
ALZHEIMER'S DISEASE 	**USD$13.0bn** by 2031[4]	**65% reduction** in Abeta aggregation **84% reduction** in cellular uptake of a-syn **89% reduction** in Tau aggregation
	4. Alzheimer's Therapeutics Market Global Opportunity Analysis 2021-2031 – Allied Market Research	*ASX Announcements dated 9th February 2023, 1st August 2023 and 3 November 2023*

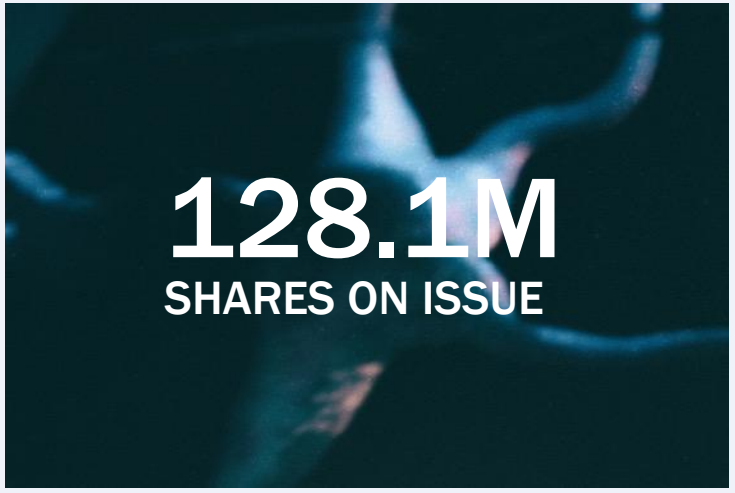
Ability to partner / licence on all indications

All indications have large addressable markets

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

KEY COMPANY METRICS





1. Cash balance as @ 31 March 2025
2. Calculated with closing price on @5th May 2025 being $0.765
3. Various ASX Announcements dated 20 January 2023, 22 March 2023, 30 March 2023, 12 September 2023

ISCHAEMIC STROKE TRIAL UPDATE

SO WHY ARE WE TARGETING STROKE FIRST?

INCIDENCE

45 SECONDS

How often someone suffers an ischaemic stroke in the US[1]

SOCIETAL IMPLICATIONS

ONLY 10%

will recover almost completely, due to the extent of brain cell damage[2]

THE IMPORTANCE OF TIME

1.9 MILLION

brain cells are attacked each minute during a stroke[3]

FIRST IN CLASS DRUG ADDRESSING LARGE UNMET NEED

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*

The Stroke Opportunity

Category	Australia	United States
Number of strokes per year	~45,000 annually[1]	~795,000 annually[2]
Cost of stroke to healthcare system per year	**AUD$5.5 billion** in healthcare costs in 2023[1]	**USD$71.55 billion in 2012** expected to increase to **USD$184.13 billion by 2030[3]**
Estimated costs associated with stroke per year	**AUD$9+ billion annually** (including healthcare and indirect costs)[1]	**USD$67 billion in 2020** expected to increase to **USD$423 billion by 2050[4]**

THOMBOLYTIC DRUG AS A COMPARABLE MARKET

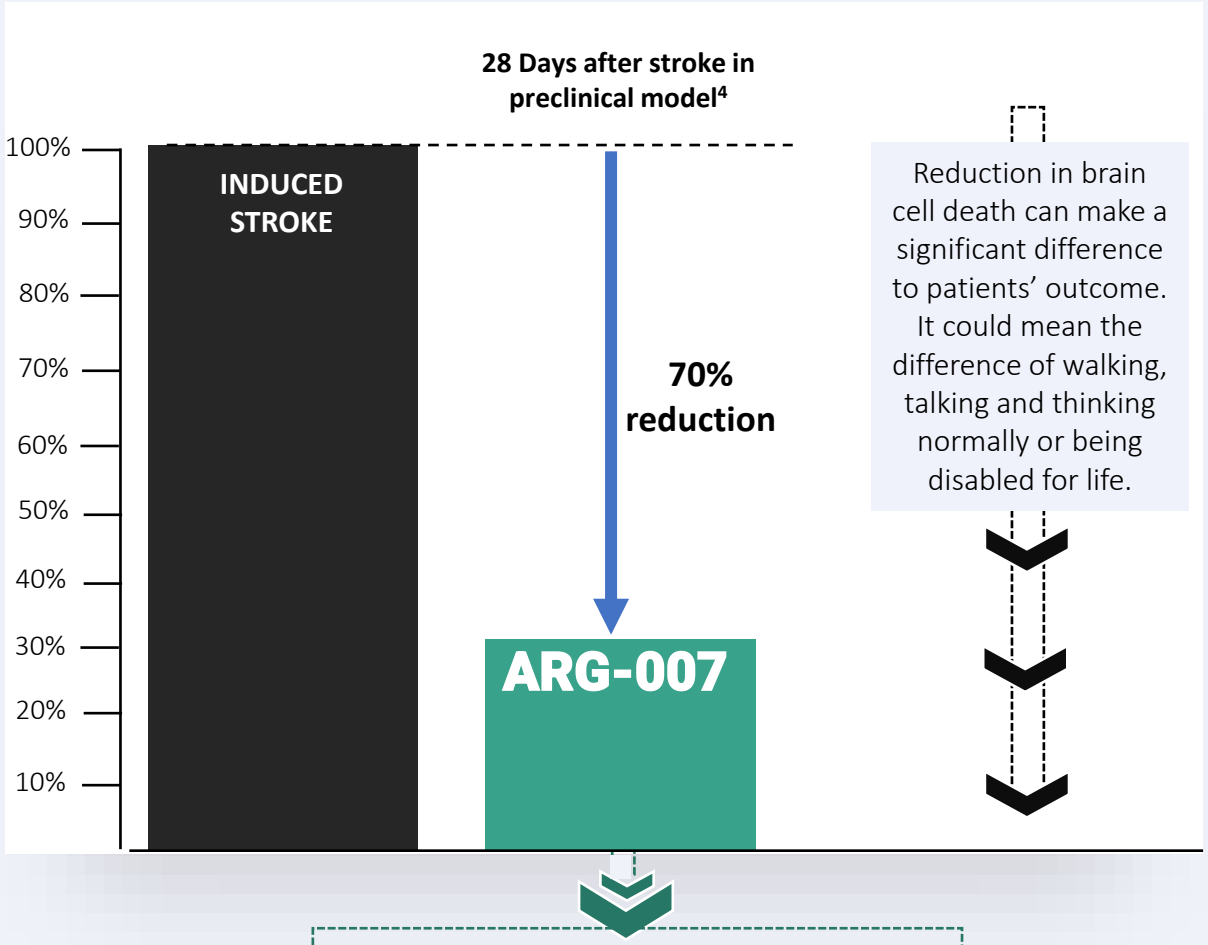
ONLY 9% OF ACUTE ISCHAEMIC STROKE PATIENTS ARE ELIGIBLE FOR THOMBOLYTICS[5]

THROMBOLYIC DRUGS CAN SELL FOR = USD$10k – 12k PER ADMINISRATION[6]
GLOBAL MARKET IN 2022 = USD 1.1B[7]
PROJECTED MARKET IN 2030 = USD 3.8B[7]

IF AGN IS SUCCESSFUL = MULTI BILLION DOLLAR OPPORTUNITY

1. *https://strokefoundation.org.au/media-centre/media-releases/2024/09/new-report-highlights-number-of-strokes-hits-all-time-high*
2. *US Centers for Disease Control and Prevention (CDC)*
3. *https://www.ahajournals.org/doi/10.1161/str.0b013e31829734f2*
4. *https://www.precedenceresearch.com/stroke-diagnostic-and-therapeutic-market*
5. *Gaukel et al. Utilization rates of intravenous thrombolysis for acute ischemic stroke in Asian countries:: A systematic review and meta-analysis. Medicine (Baltimore). 2023 Oct 20;102(42)*
6. *Kleindorfer D et al. Cost of Alteplase Has More Than Doubled Over the Past Decade. Stroke. 2017 Jul;48(7):2000-2002.*
7. *https://www.verifiedmarketresearch.com/product/thrombolytic-drug-market/*

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

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 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

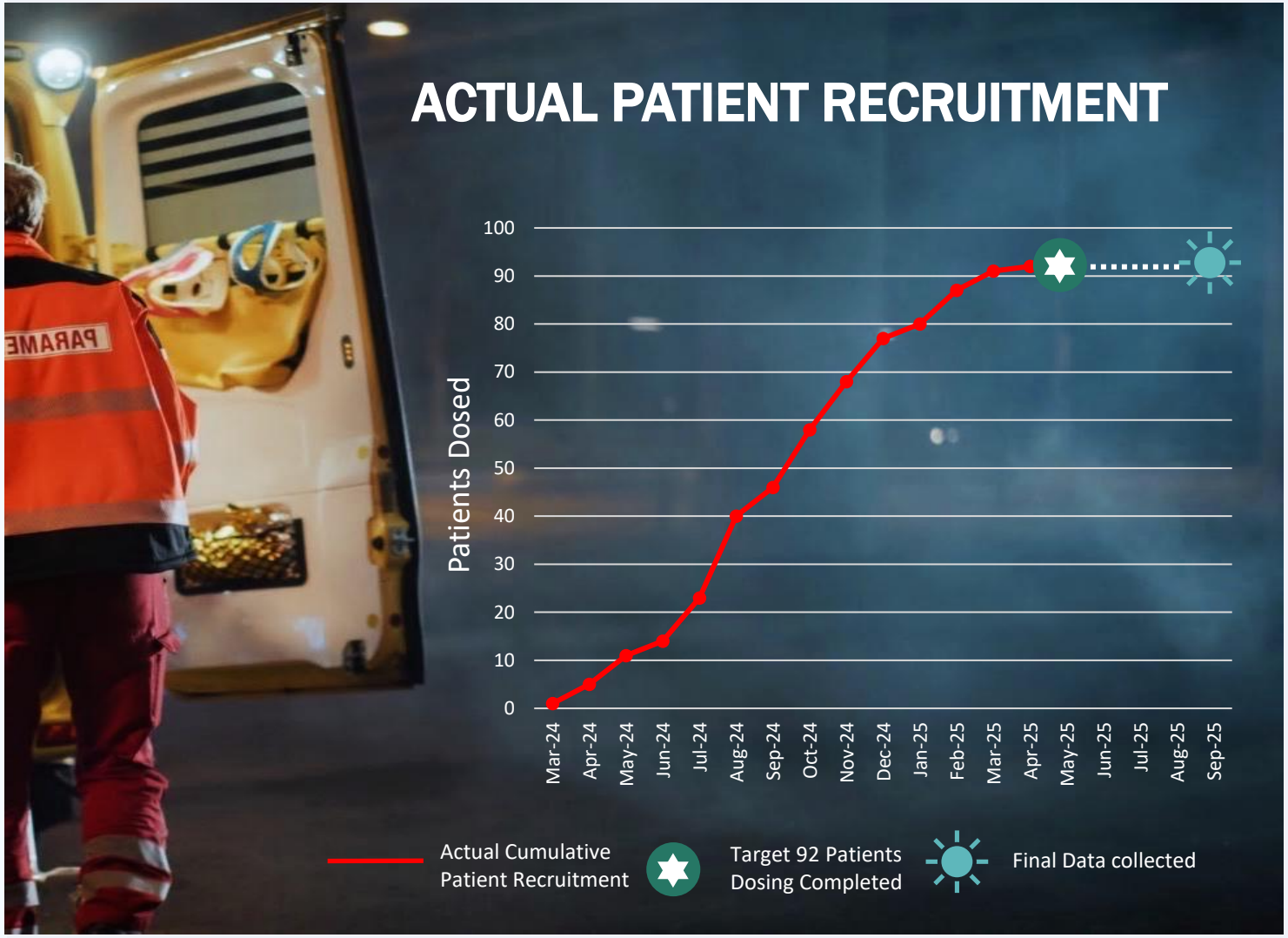
- Administration of **0.3mg/kg** ARG-007 or saline placebo
- All patients receive thrombectomy

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)

Potential benefits only. ARG-007 is under development and subject to clinical validation.

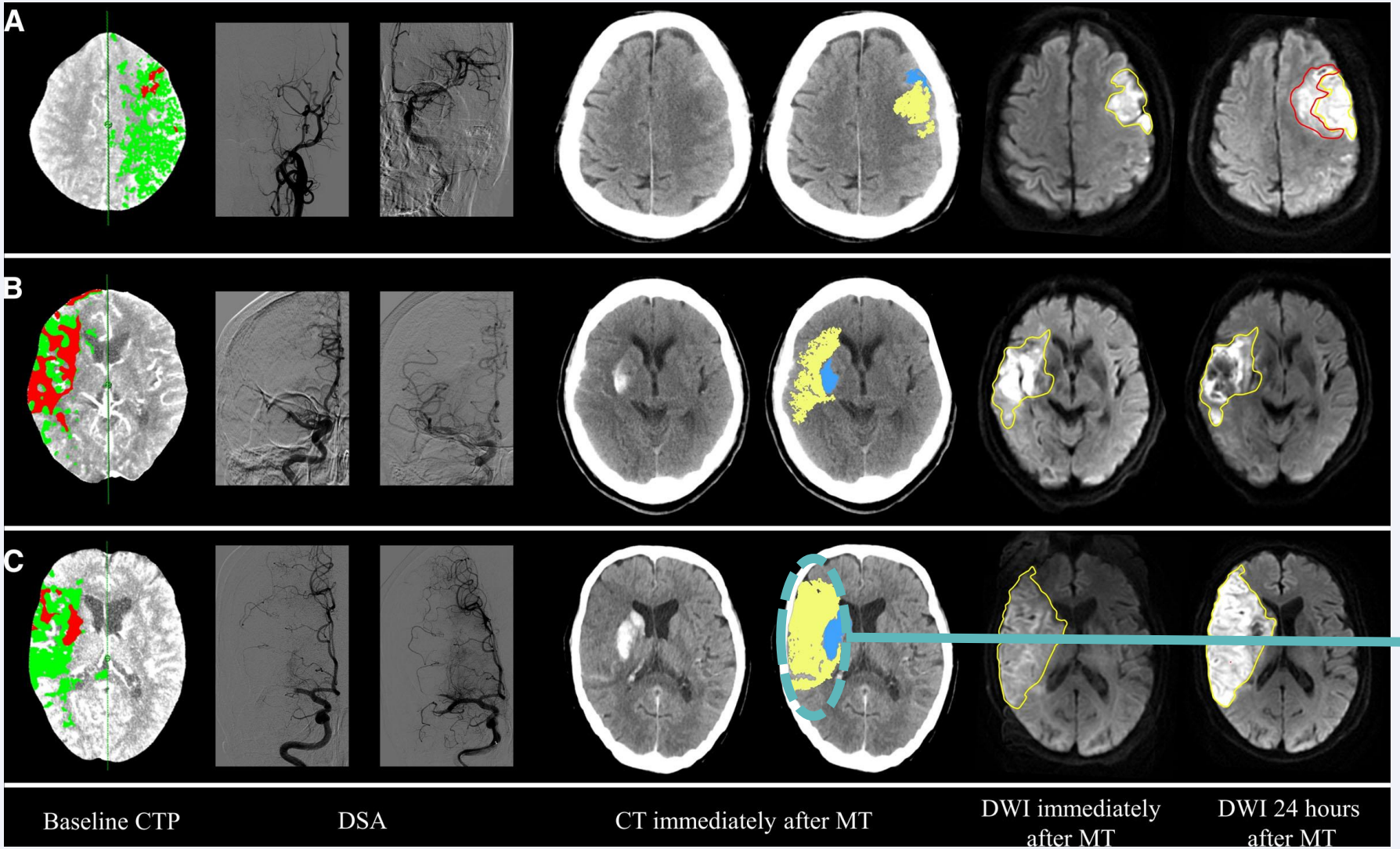
PHASE 2 CLINICAL TRIAL IN STROKE



- PATIENT DOSING COMPLETED AT 8 AUSTRALIAN HOSPITALS
- 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
- TOPLINE DATA DUE Q3 CALENDAR YEAR 2025.

EXAMPLE OF WHAT PHASE 2 TRIAL HOPES TO ACHIEVE:

REDUCING INFARCT VOLUME (i.e. BRAIN DEATH) FOLLOWING STROKE & THROMBECTOMY



Infarct core: permanent brain cell death (i.e. cannot be saved)

Vulnerable Penumbra: Surrounding tissue that is vulnerable to dying (i.e. still alive, but likely to die without protection)

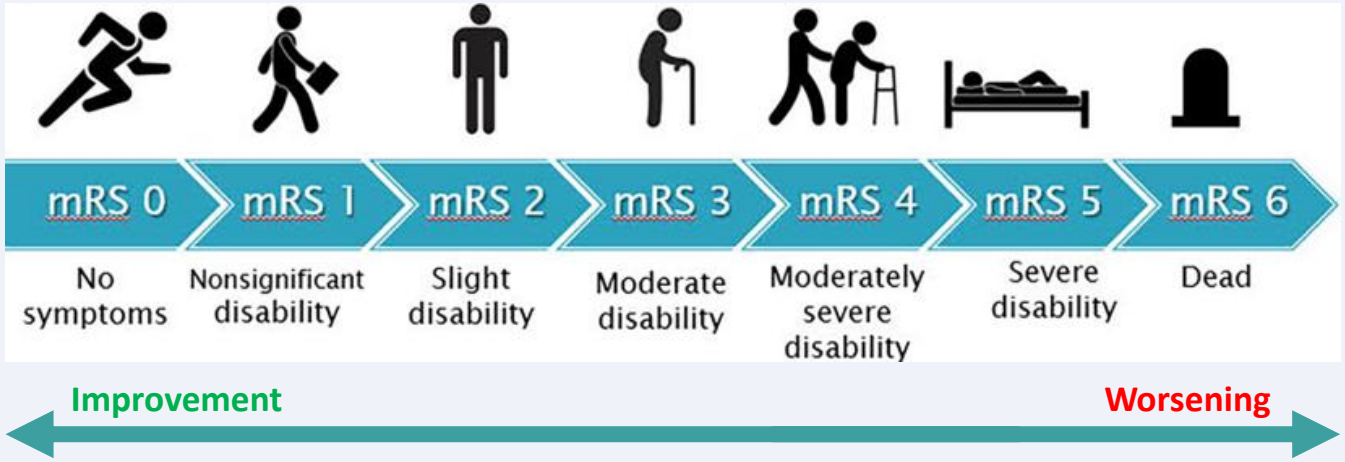
ARG-007 aims to <u>reduce infarct volume</u> (i.e. brain death) by protecting the Vulnerable Penumbra from dying following stroke & thrombectomy

Zhou Y, et al, Reperfusion Injury Is Associated With Poor Outcome in Patients With Recanalization After Thrombectomy. Stroke. 2023 Jan;54(1):96-104.

WHAT DOES A REDUCTION IN INFARCT MEAN FOR PATIENTS?

***Reducing infarct volume** after an ischemic stroke is a crucial measure because data suggests it is the **strongest predictor of better outcomes**, including improved neurological function, independence, and lower mortality.*[1]

mRS Scale (i.e. a measure of a patient's disability)

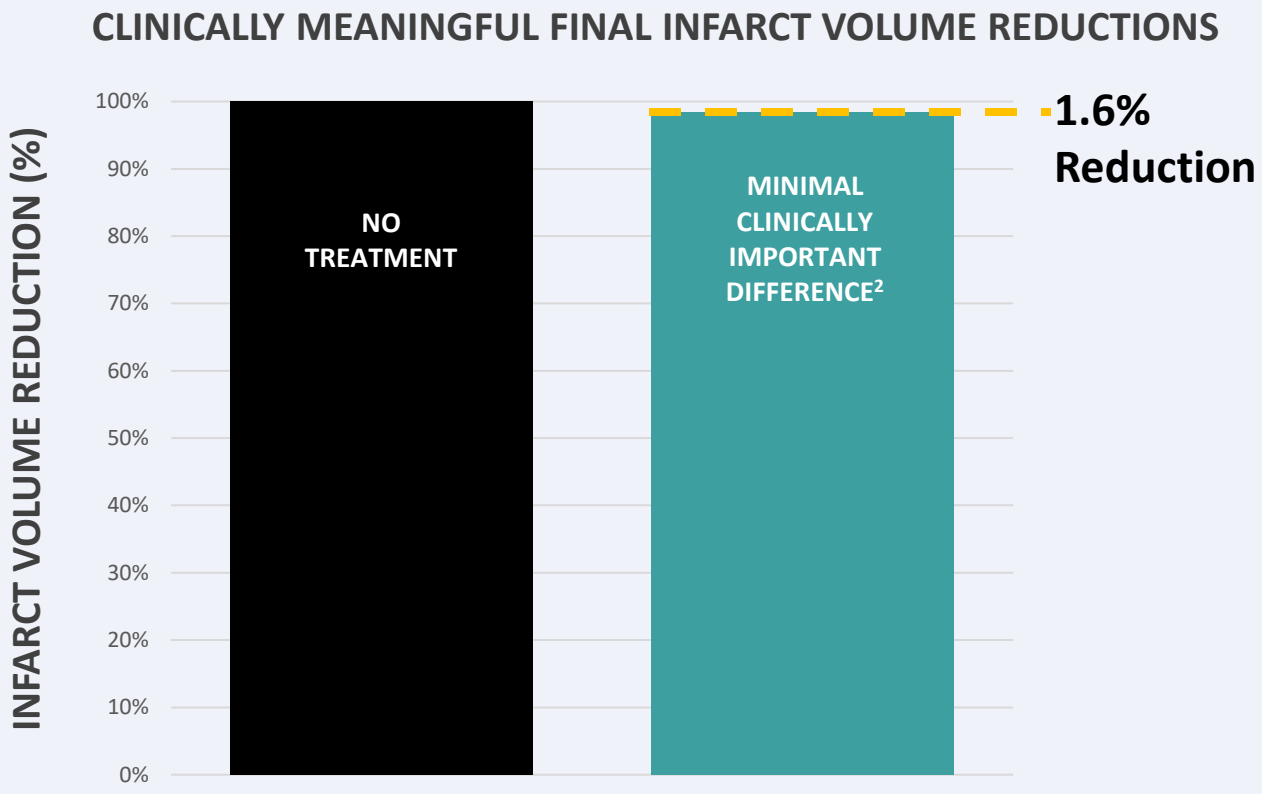


Ultimately, ARG-007 needs to move more people to the left on the mRS (into 0-2). If the Phase 2 trial shows a reduction in infarct volume, there will be a greater chance of seeing improved mRS in a larger pivotal trial (i.e. Phase III)

Greater independence = greater savings to healthcare system

1. Abraham S, et al. Automatically quantified follow-up imaging biomarkers predict clinical outcomes after acute ischemic stroke. Front Neurol. 2025 Mar 19;16:1483138

HOW MUCH BRAIN DO YOU NEED TO SAVE?



- A 1.6% decrease in infarct volume (decrease in brain cell death) is **the minimum amount** of decrease deemed to be clinically important[1]. This decrease, on average, results in **1.3 more patients achieving** out of 100 achieving functional independence (mRS 0-2).
- Studies have shown a decrease of **5%, 11.5% and 17%** would results in **5, 10 and 15** more patients out of **100**, respectively, achieving functional independence (mRS of 0-2). This means 5, 10 and 15 more patients per 100 who would move from being severely or moderately disabled to having no or only a slight disability[1].
- **There are currently no approved drugs to reduce brain death following stroke, therefore any statistically significant reduction in infarct volume beyond 1.6% would be seen as a positive outcome.**

EVEN A SMALL REDUCTION IN INFARCT VOLUME INCREASES THE CHANCE A PATIENT WILL WALK, TALK & CARE FOR THEMSELVES

1. *Liao NC, Bahr Hosseini M, Saver JL. Clinically important effect sizes for clinical trials using infarct growth reduction as the primary outcome: a systematic review. J Neurointerv Surg. 2023 Oct 31 – average final infarct volume across all studies is 38.4mL.*
2. *From Liao et al 2023 - Minimal clinically important difference-outcome specific is defined as the smallest change in a treatment outcome measure that a patient would consider of value, if the treatment producing the outcome was simply implemented, safe and inexpensive.*

INVESTIGATIONAL NEW DRUG & FAST TRACK APPLICATIONS SUBMITTED TO FDA

The IND application for ARG-007 in AIS has now been submitted with the FDA. Regulatory advice has indicated there are advantages to including a Fast Track Application with the IND application, therefore a Fast Track Application was submitted alongside the IND.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast track designation provides:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for *Accelerated Approval and Priority Review, if relevant criteria are met*
- *Rolling Review*, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

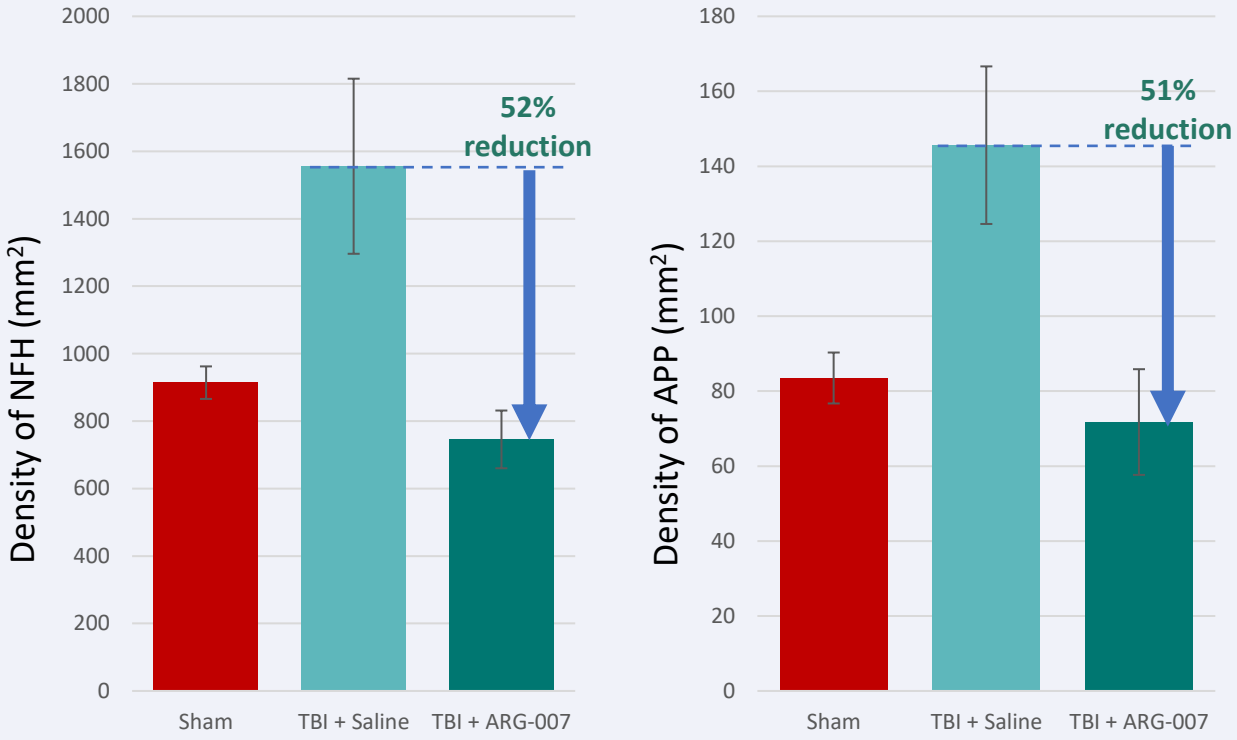
1. ASX Announcements Dated 15 November 2023, 25 March 2024 and 30 October 2024.

THE OPPORTUNITY FOR ARG-007 IN OTHER INDICATIONS

ARG-007 POTENTIAL IN TBI – RAT DATA

- Estimated USD$18.6bn market size by 2031[1]
- ARG-007 has shown efficacy in pre-clinical studies[2]
- Awarded A$1.2m grant to advance pre-clinical studies[3]

ARG-007 SIGNIFICANTLY REDUCES NFH PROTEIN AND APP FOLLOWING TBI[2]



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).

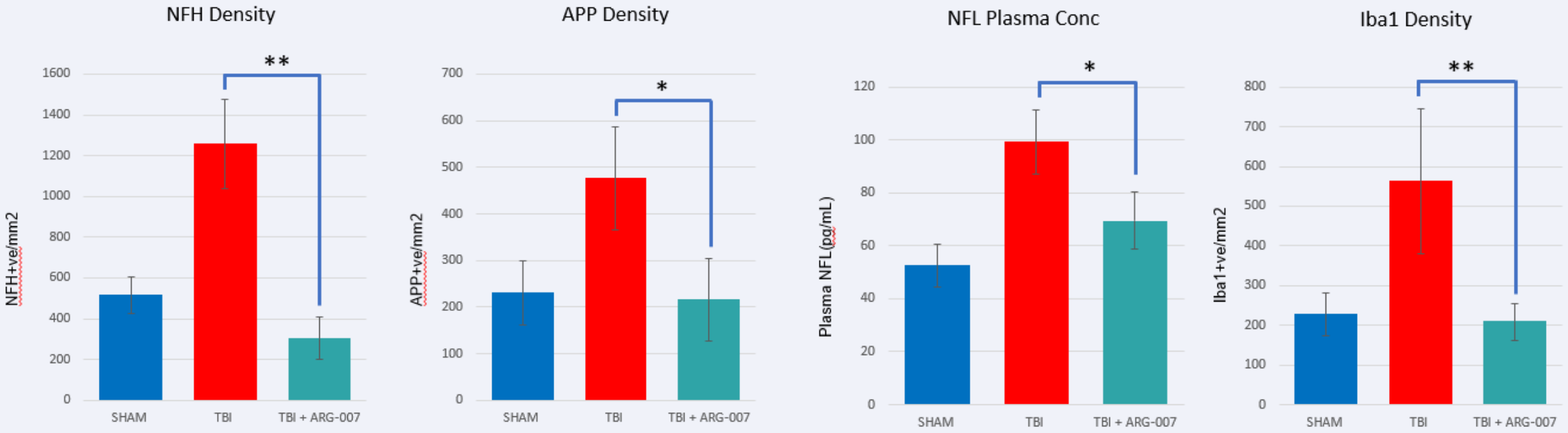
1. Traumatic brain injuries assessment market research, 2031 – Allied Market Research

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

CONFIRMED IN LARGER RAT STUDY

ARG-007 SIGNIFICANTLY REDUCES KEY TBI BIOMARKERS[1]



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), amyloid precursor protein (APP), neurofilament light (NFL) and inflammatory marker Iba1.

1. ASX Announcement titled 'ARG-007 shows significant neuroprotection in main traumatic brain injury study' 4 February 2025

ARG-007 POTENTIAL IN TBI – FERRET DATA

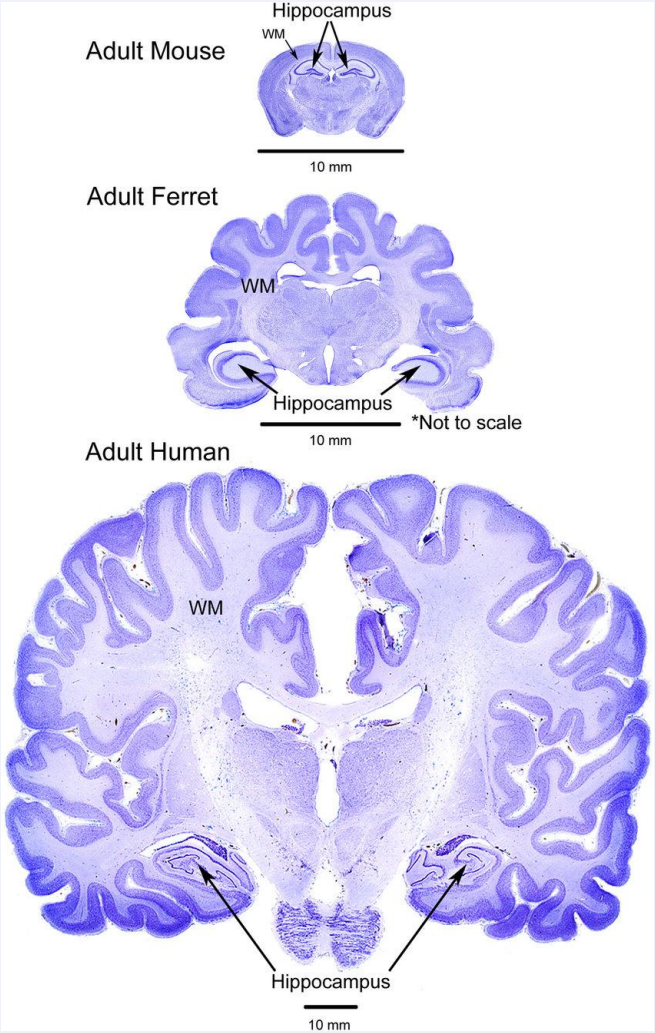
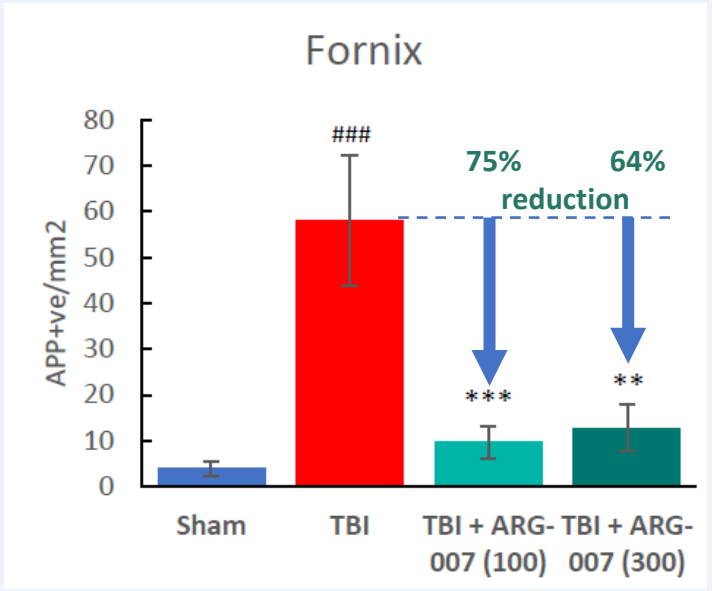
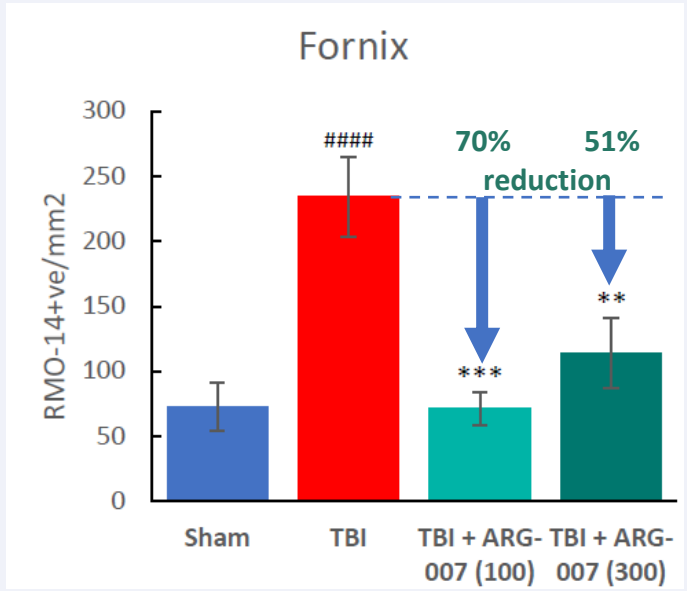


Image reference – Schwerin et al 2017, Establishing the ferret as a gyrencephalic animal model of traumatic brain injury: Optimization of controlled cortical impact procedures, Journal of Neuroscience Methods

ARG-007 SIGNIFICANTLY REDUCES AMYLOID PRECURSOR PROTEIN (APP) AND NEUROFILAMENT M-14.9 (RMO-14) & FOLLOWING TBI[1]

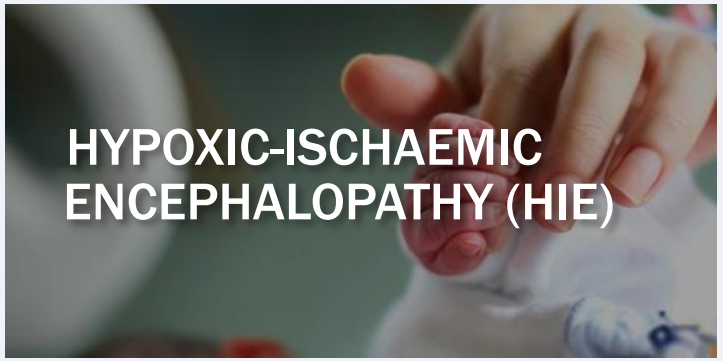




ARG-007 was found to protect brain cells in the injured brain by significantly reducing the accumulation of proteins associated with injury in brain cell following TBI, specifically APP and RMO-14. ### TBI injury is significantly difference from sham, confirming injury impairment. ***p<0.001, **p<0.01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

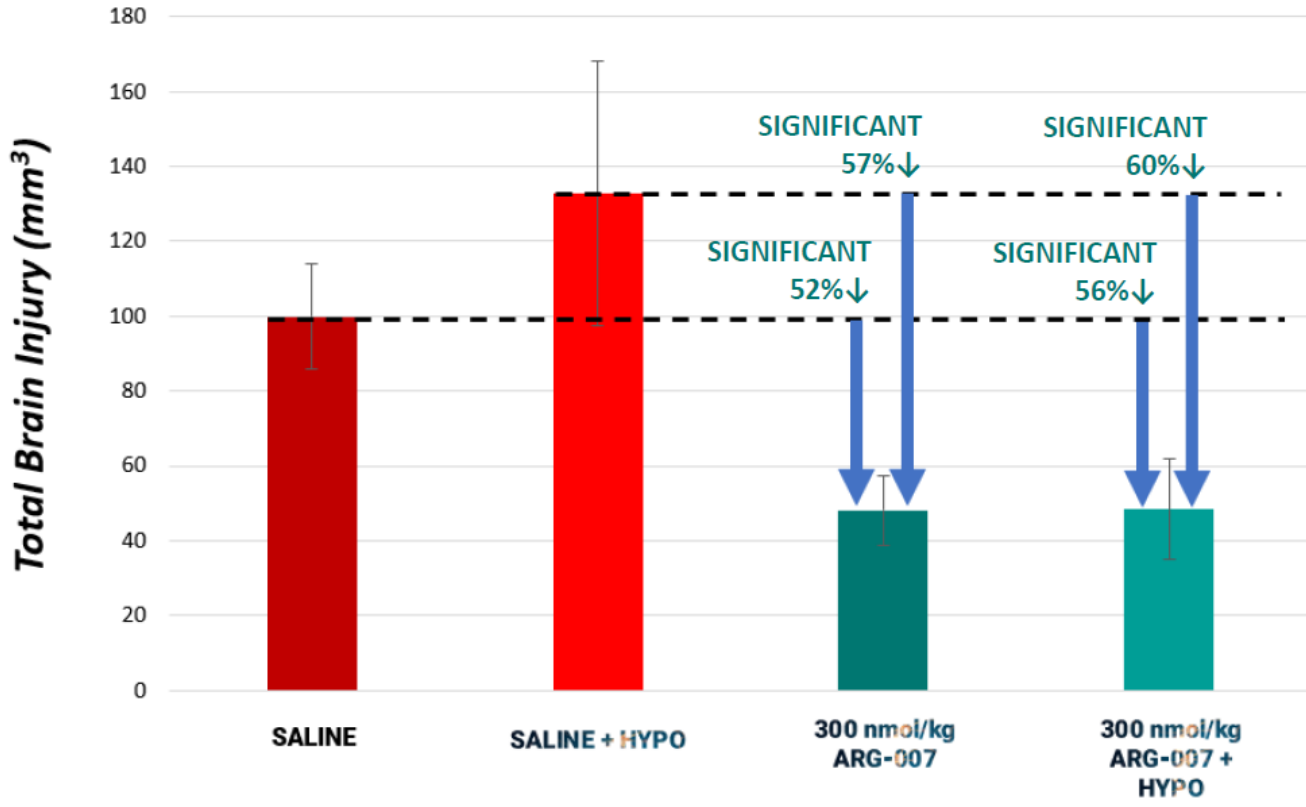
1. ASX Announcement dated 15 May 2024, ARG-007 Significantly Reduces Effects of Traumatic Brain Injury in Preclinical Study

ARG-007 POTENTIAL IN HIE



- HIE occurs in 1.5 to 2.5 births per 1000[1]
- Current standard of care is hypothermia
- Awarded A$2.5m grant to advance pre-clinical studies[2]

TOTAL BRAIN INJURY AT 4 WEEK POST HIE WITH ARG-007 TREATMENT OR ARG-007 WITH STANDARD OF CARE HYPOTHERMIA[3]



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

NEAR-TERM CATALYSTS

Q2 CY25

- Investigational New Drug Application and Fast Track Application to be submitted to the FDA
- Phase 2 Dosing completed
- TBI Preclinical Data
- Open IND

Q3 CY25

- Release of Phase 2 topline data
- Fast Track Designation

Q4 CY25

- HIE preclinical data

INVESTMENT HIGHLIGHTS

1# SOLVING LARGE UNMET NEEDS

Nervous system disorders are the biggest cause of poor health globally[1]. **Currently there are no marketed safe, early intervention therapeutics capable of protecting the brain** from damage following stroke[2]. 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.

1 - Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. The Lancet Neurology, published online March 2024. https://doi.org/10.1016/S1474-4422(24)00038-3
2 - Stroke Foundation; accessed 3 May 2021, <https://strokefoundation.org.au/en/About-Stroke/Learn/Treatment-for-stroke/Early-treatment-after-a-stroke>

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