ARGENICA TO PRESENT ARG-007 DATA AT STROKE 2023 SCIENTIFIC CONFERENCE

Perth, Australia; 24 AUGUST 2023 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other brain injury, is pleased to announce Dr David Blacker, Head of Argenica's Clinical Advisory Committee, is presenting a talk today at the Joint Annual Scientific Meeting of the Stroke Society of Australasia (SSA) and Smart Strokes (Stroke 2023) in Melbourne, Victoria.

The talk is titled *A Phase 1, double-blind, randomised, placebo-controlled, sequential-group study to assess the safety, tolerability and pharmacokinetics of single ascending doses of ARG-007 in healthy participants* to be presented in **Session 7.3 - Novel Approaches to Acute Stroke Care**.

The slides are attached to this announcement.

Argenica's Managing Director, **Dr Liz Dallimore said**: "We are delighted that Dr Blacker has been invited to present our data on the safety of ARG-007 in healthy volunteers at the Stroke 2023 Conference. The conference will also provide the Company with the opportunity to engage with clinicians on our upcoming Phase 2 clinical trial in acute ischaemic stroke."

This announcement has been approved for release by the Board of Argenica.

For more information please contact: info@argenica.com.au

ABOUT ARGENICA

Argenica (ASX: AGN) is developing novel therapeutics to reduce brain tissue death after stroke and other types of brain injury and neurodegenerative diseases to improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007, has been successfully demonstrated to improve outcomes in pre-clinical stroke models, traumatic brain injury (TBI) and hypoxic ischaemic encephalopathy (HIE). The Company has recently completed a Phase 1 clinical trial in healthy human volunteers to assess the safety and tolerability of a single dose of ARG-007. Argenica is now progressing towards a Phase 2 clinical trial in ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions, including in TBI, HIE and Alzheimer's Disease.

ARGENICA THERAPEUTICS

perron institute for neurological and translational science

THE UNIVERSITY OF WESTERN AUSTRALIA

linear

A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Sequential-Group study to Assess the Safety, Tolerability, and Pharmacokinetics of Single Ascending Dose of ARG-007 in Healthy Participants

David Blacker A.M., Andrew Redfern, Meghan Thomas, Samantha South, Neville Knuckey, Bruno Meloni

SSA Meeting, AUGUST 2023

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Author disclosures

David Blacker, Bruno Meloni, Neville Knuckey: named inventors on patent, hold founder equity shares and other share types within Argenica Therapeutics.

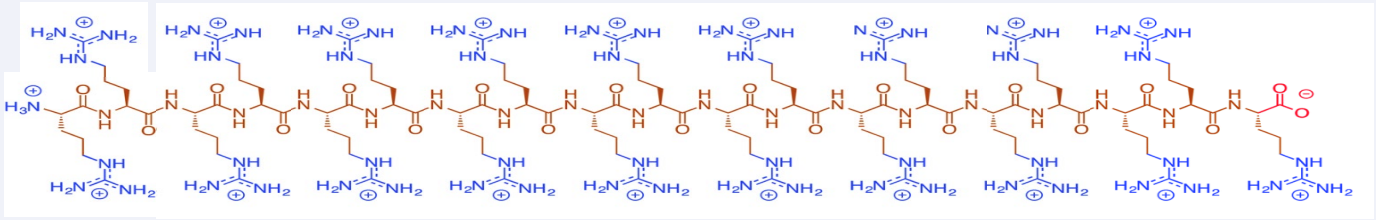
Samantha South: Founding Director of Argenica and holds founder equity shares.

Meghan Thomas: Employed by Argenica and has share options.

ARG-007: POLY ARGININE 18 (R18D)

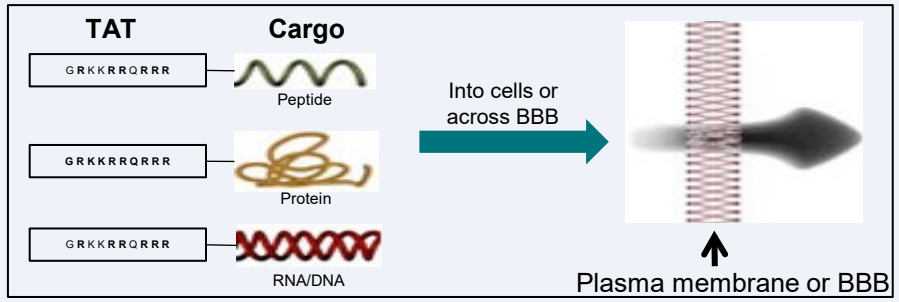
- Our lead peptide is ARG-007
  - 18 Arginine

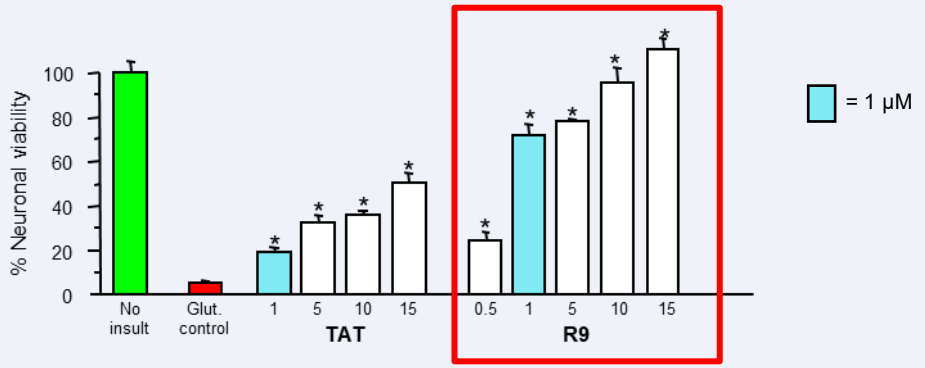
  - Net charge = +18



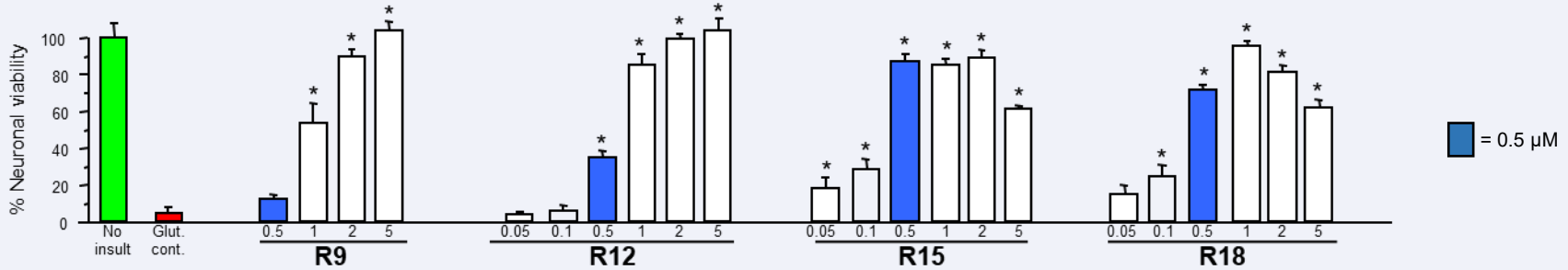
CATIONIC ARGININE RICH PEPTIDES (CARPs)

- CARPs are commonly used as cell penetrating peptides
  - Can enter cells and cross the blood-brain-barrier
  - Used as carrier molecules to deliver agents into the Central Nervous System.
  - One of the most commonly used CARPs is the TAT peptide:
    - GRKKRRQRRR (R = arginine; charge = +8;)
    - TAT peptide displayed modest neuroprotection in neuronal glutamate excitotoxicity model
    - Nine Arginine (R9; charge = +9) was more neuroprotective[1]





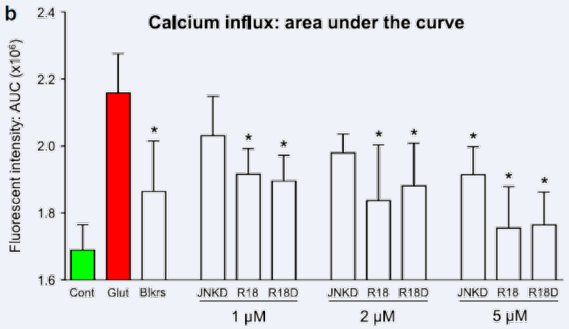
- Increasing the number of Arginines (and positive charge) increased the neuroprotective capabilities[2]



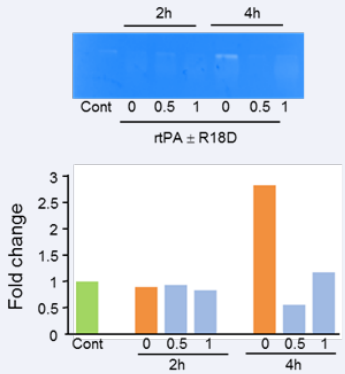
[1]Meloni et al., 2014. Cell Mol Neurobiol. 34:173-181. [2]Meloni et al., 2015. J Cere Blood Flow & Met. 35:993-1004

MULTIMODAL MECHANISM OF ACTION

Prevents Ca^{2+} influx[1]



Astrocytes: MMP9 activity[3]



STROKE

Glutamate release and receptor activation — ARG-007

ARG-007 — Ca^{2+} influx

Membrane homeostatic imbalance and depolarisation

Ca^{2+} influx sensitive enzymes (Phospholipases and proteases) MMPs — ARG-007

Toxic cytokines — ARG-007

ARG-007 — Free radical formation

ARG-007 — Oxidative stress

REPERFUSION

APOPTOSIS

ARG-007 — Mitochondrial permeability transition

Cytochrome C release

Caspase-9 activation

Caspase-3 activation

Penumbra
ATP
Core
ATP
NECROSIS

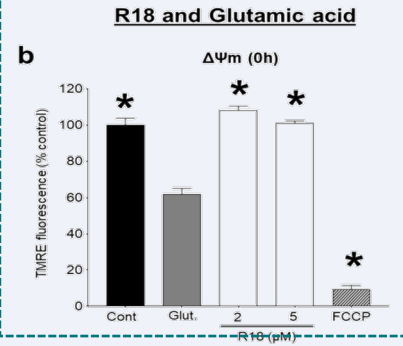
Loss of integrity/ cerebral oedema — ARG-007

Inflammation — ARG-007

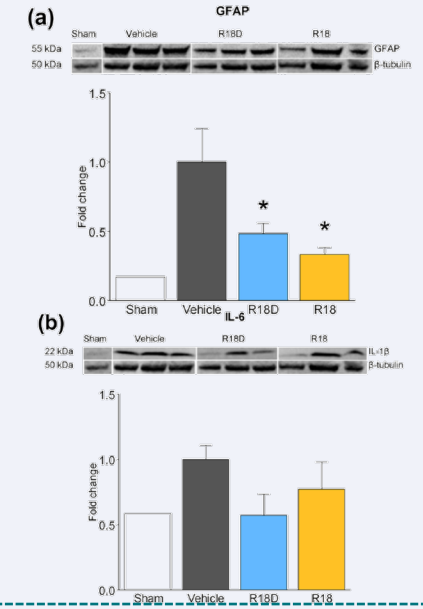
DNA damage

CELL DEATH

Restores mitochondrial membrane potential[2]



Blocks inflammation[4]



ARGENICA THERAPEUTICS

[1]Edwards et al., 2018. Mol Brain. 11(1):8. [2]MacDougall et al., 2020. Molecules. 25(13):2977. [3]Kenna et al., 2020. Neurochem Res 45(5):1215-1229. [4]Chiu et al., 2020. Curr Ther Res Clin Exp. 19:92:100584

PHASE 1 CLINICAL TRIAL

PARTICIPANTS

4 cohorts, with each cohort receiving a different dose of ARG-007 (8 participants in each cohort, 2 placebo and 6 receiving ARG-007).

LOCATION

Single site study conducted at the Linear Clinical Research facility in Western Australia.

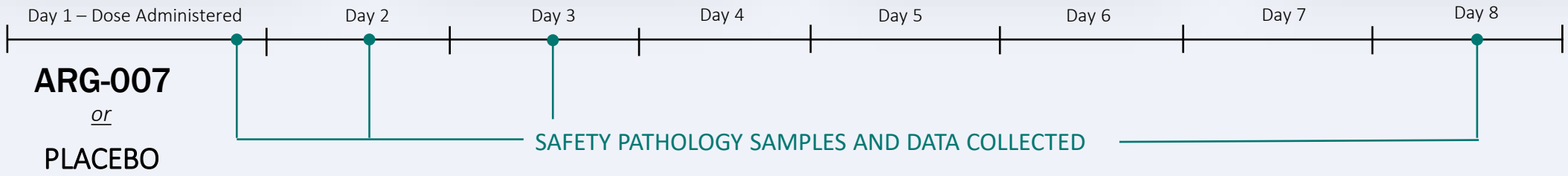
DURATION

First healthy adult dosed on 17th October 2022[1], forth and final cohort completed dosing on 21 December 2022[2].

DESIGN

Double-blind, randomised study where participants either receive a dose of ARG-007 or a placebo.

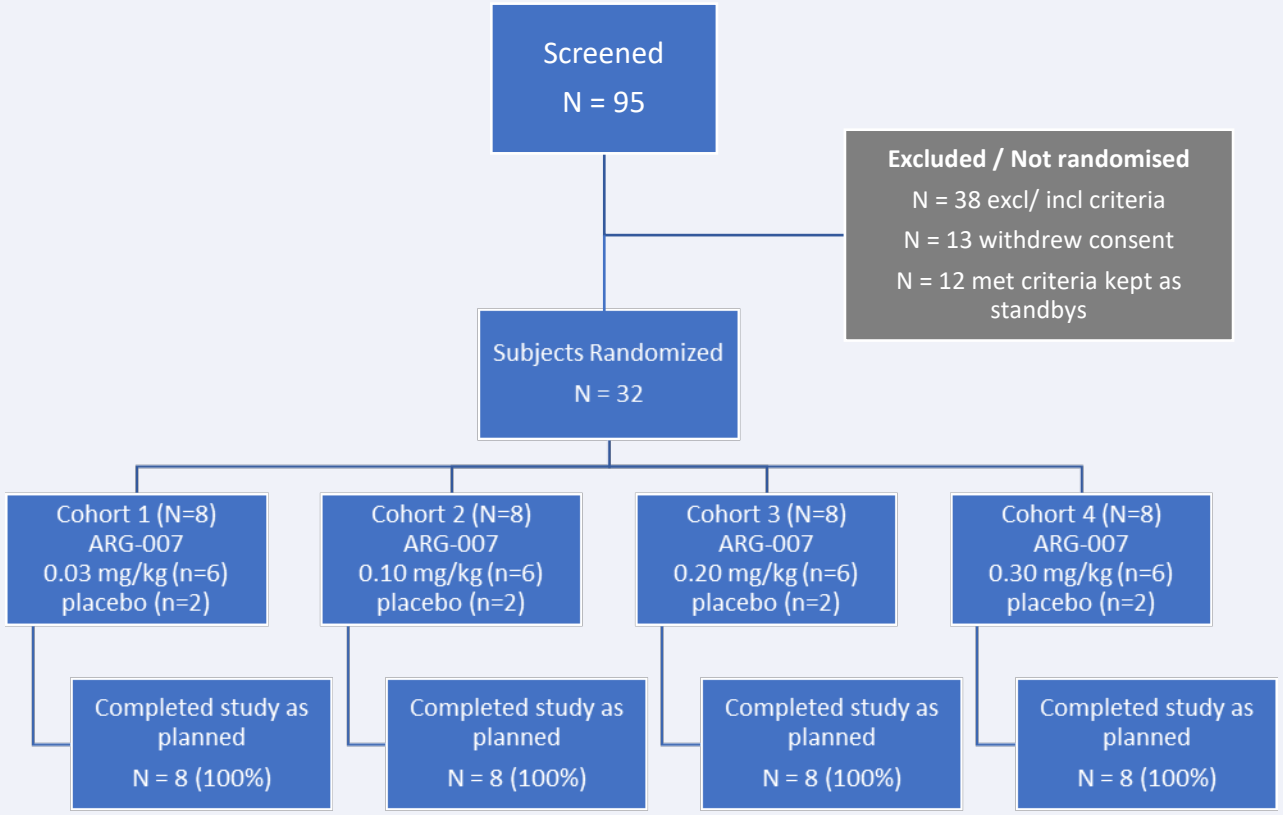
PROCEDURE OUTLINE FOR EACH PARTICIPANT



[1]ASX Announcement titled 'First healthy adult subject dosed in phase 1 trial of ARG-007' 12 October 2022
[2]ASX Announcement titled 'Successful completion of phase 1 clinical trial dosing and commencement of phase 2 trial planning' 21 December 2022

SUBJECT OVERVIEW & EXPOSURE

- 95 subjects screened
- 32 randomized:
  - Mean age = 36.2 (range 18 – 62 years)
  - 53.1% female
- Single 10 minute IV
- ARG-007 mean exposure:
  - Cohort 1 (0.03 mg/kg) = 2.21 mg
  - Cohort 2 (0.10 mg/kg) = 7.89 mg
  - Cohort 3 (0.20 mg/kg) = 14.77 mg
  - Cohort 4 (0.30 mg/kg) = 21.72 mg



ASX Announcement titled 'Interim Phase 1 safety report confirms safety of ARG-007' 6 March 2023
ASX Announcement titled 'Final Phase 1 clinical trial report confirms Argenica successfully passes critical milestone' 15 May 2023

RESULTS: PRIMARY OBJECTIVE

❖ **Safety and tolerability of single escalating doses of ARG-007**

Safety was evaluated from the analysis of:

1) Incidence of SAEs and SUSARs
2) Clinically significant changes from baseline in laboratory evaluations of:
   - Hematology
   - Clinical Chemistry
   - Coagulation
   - Urinalysis
3) Clinically significant changes from baseline:
   - ECG
   - Vital Signs
   - Physical Examination
4) Incidence of AEs
5) Severity of AEs

SAEs or SUSARs: no serious, severe, life threatening or fatal TEAEs reported during the study.

Hematology: no dose-related trend in changes over time for any treatment groups

Clinical Chemistry: no dose-related trend in changes over time for any treatment groups

Coagulation: no dose-related trend in changes over time for any treatment groups

Urinalysis: no dose-related trend in changes over time for any treatment groups

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ECG: no dose related trends in ECG or adverse events, related to these assessments.

Vital signs: no dose related trends in vital signs or adverse events, related to these assessments.

Physical examination: no dose related trends in physical examinations or adverse events, related to these assessments

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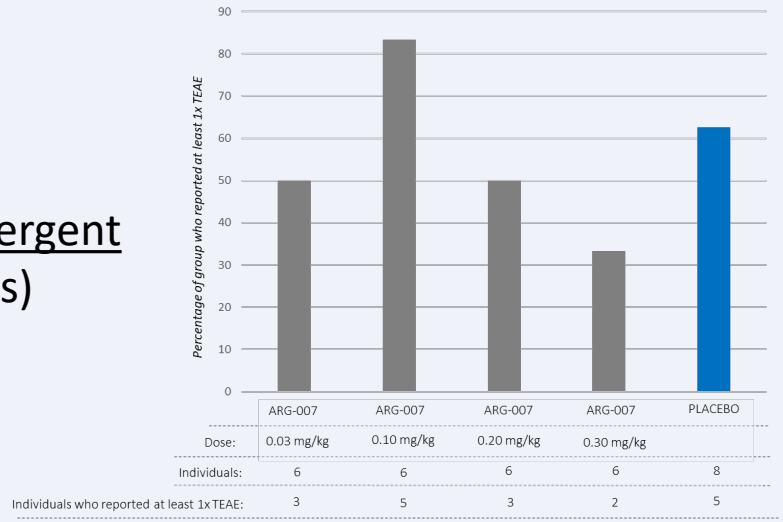
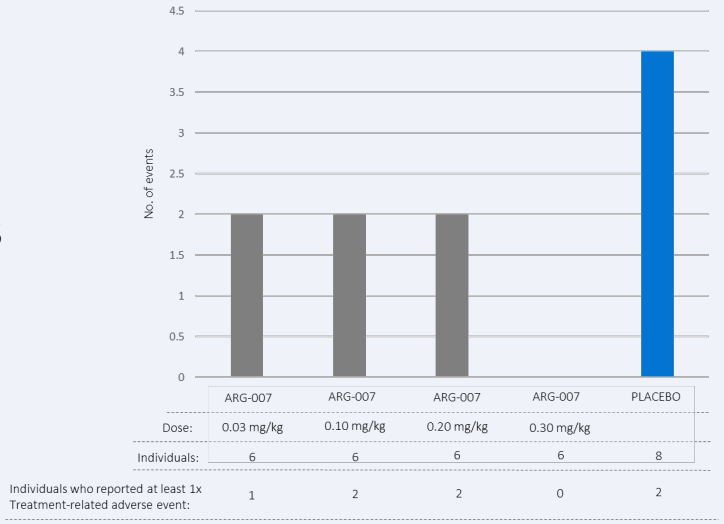
Treatment Emergent AEs (TEAEs)



Related TEAEs



TEAEs encompass all adverse events, including signs, symptoms or underlying medical conditions that emerge or worsen during the study.
Related TEAEs are defined as TEAEs where the relationship to the investigational product was reported as 'possibly', 'likely' or 'definitely' related.

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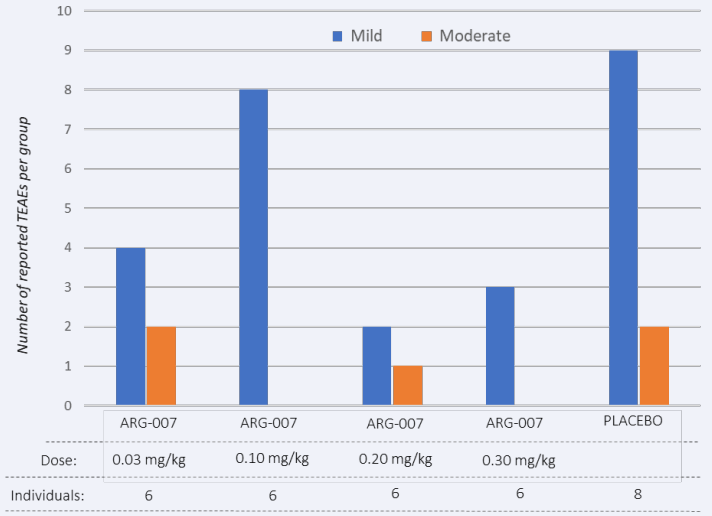
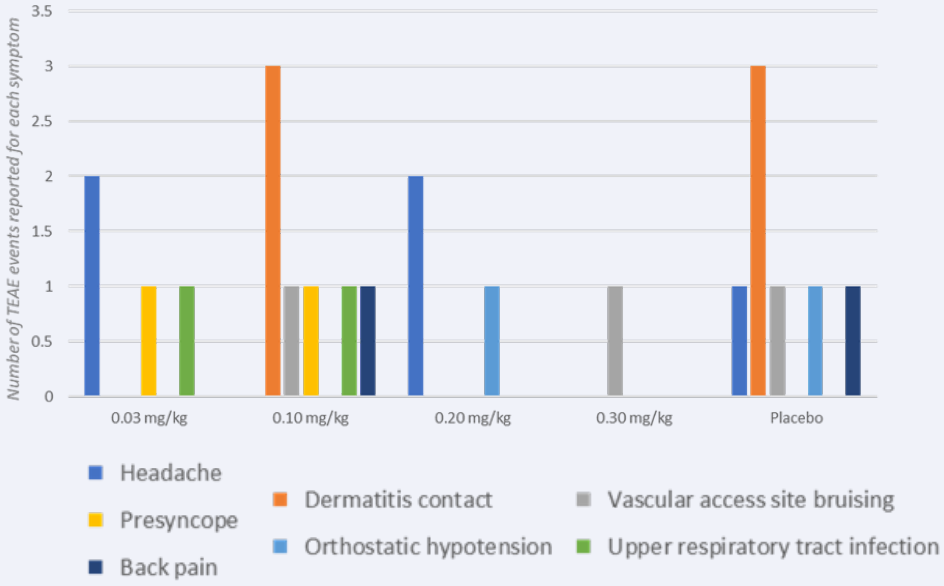
Severity of TEAEs



Type of TEAEs



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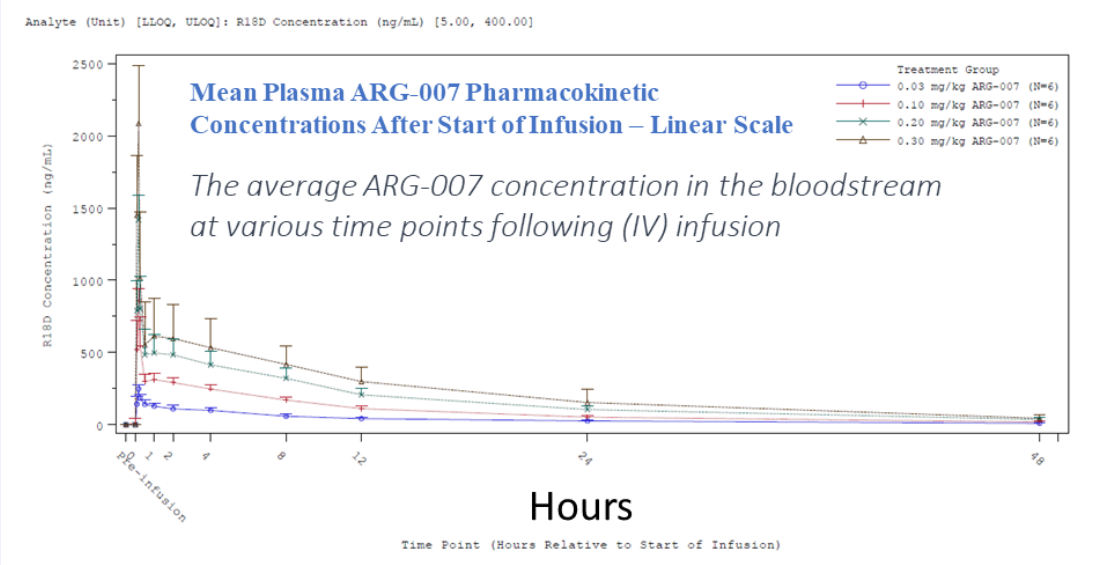
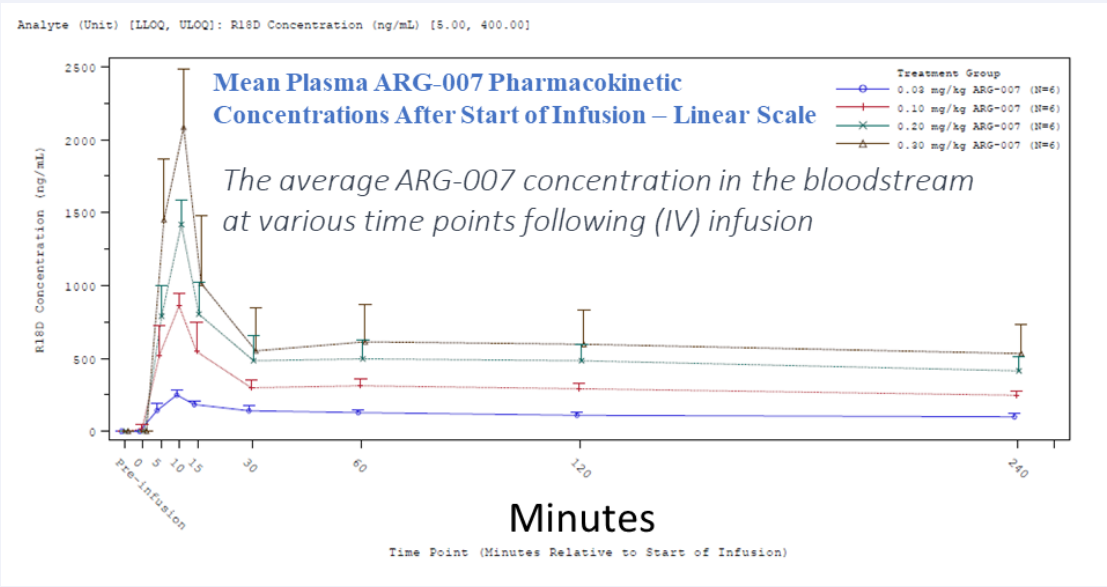
RESULTS: SECONDARY OBJECTIVE

❖ **Determine the pharmacokinetic profile of ARG-007 following a single dose**

- The highest concentration of ARG-007 in the plasma observed at the end of infusion (10 minutes).
- Concentrations of ARG-007 were detected in the bloodstream up to 48 hours after administration.
- Half-life 12.4 to 15.8 hours
- The fast-acting nature of ARG-007 is critical to maximise the protection of neurons following acute ischaemia, such as in stroke.





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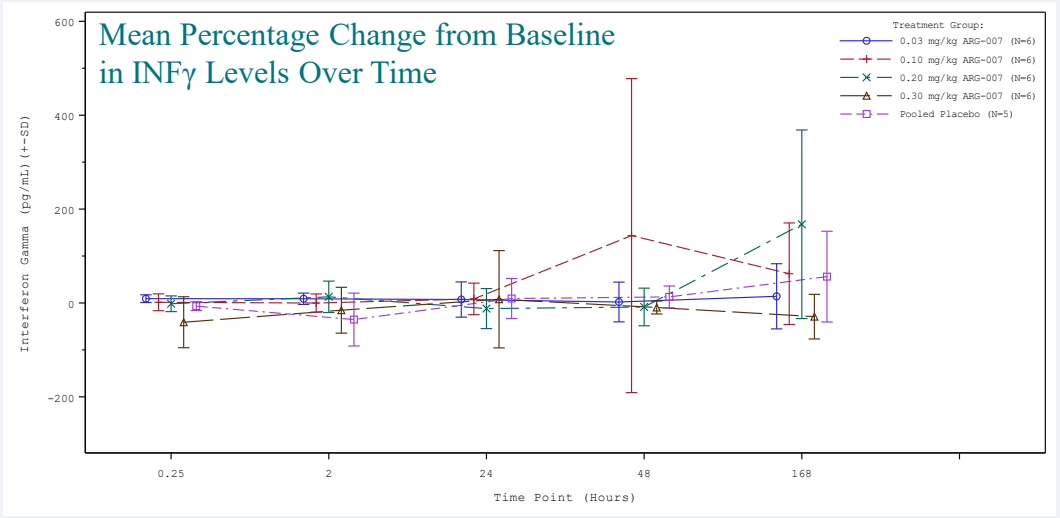
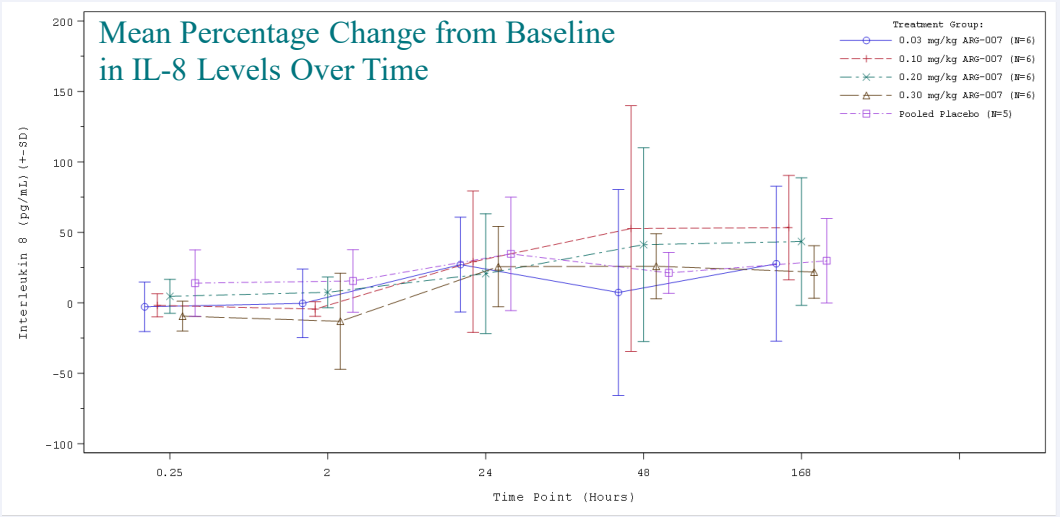
RESULTS: EXPLORATORY OBJECTIVE

- **Assess the immune response of ARG-007 following a single dose**
  - The presence of cytokines (TNFα, INFγ, IL-1β, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12) were analysed to investigate whether ARG-007 caused an immune reaction.
  - The only cytokines that were detectable were **IL-8 and INFγ**; neither of which showed any notable trends in change from baseline over time, at any dose.





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Phase 1 primary endpoint successfully achieved:

DOSES OF ARG-007 PROVED SAFE & WELL-TOLERATED, WITH NO SERIOUS ADVERSE EVENTS OR IMMUNE RESPONSE DETECTED.

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NEXT STEPS

- **Phase 2 study of ARG-007 in Ischaemic Stroke Patients ("SEANCON")**

THANK YOU