
ARGENICA THERAPEUTICS
PHASE 1 CLINICAL TRIAL
OVERVIEW & ROADMAP
OCTOBER 2021

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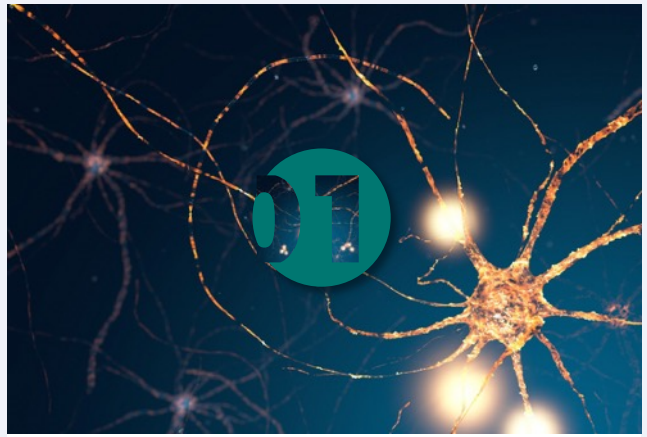


Roadmap to Argenica's Phase 1 Clinical Trial

Phase 1 Clinical Trial overview and primary objectives

The opportunity in stroke

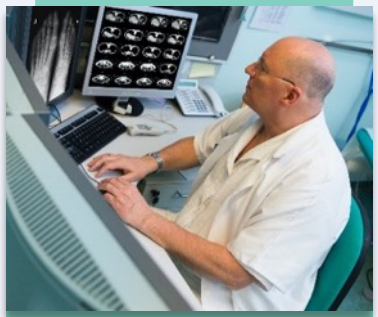
PHASE 1 CLINICAL TRIAL ROADMAP

PHASE OF DEVELOPMENT

BASIC RESEARCH

Argenica has gone through an extensive discovery phase through basic research studies

ANIMAL STUDIES



PRE-CLINICAL STUDIES

Currently undertaking regulatory required efficacy and safety research in animals

HEALTHY HUMANS

PHASE 1

Confirmation of safety, such as side effects, in a small number of healthy persons

STROKE VICTIMS

PHASE 2

Confirmation of effective safe dosage and administration method in stroke patients

STROKE VICTIMS

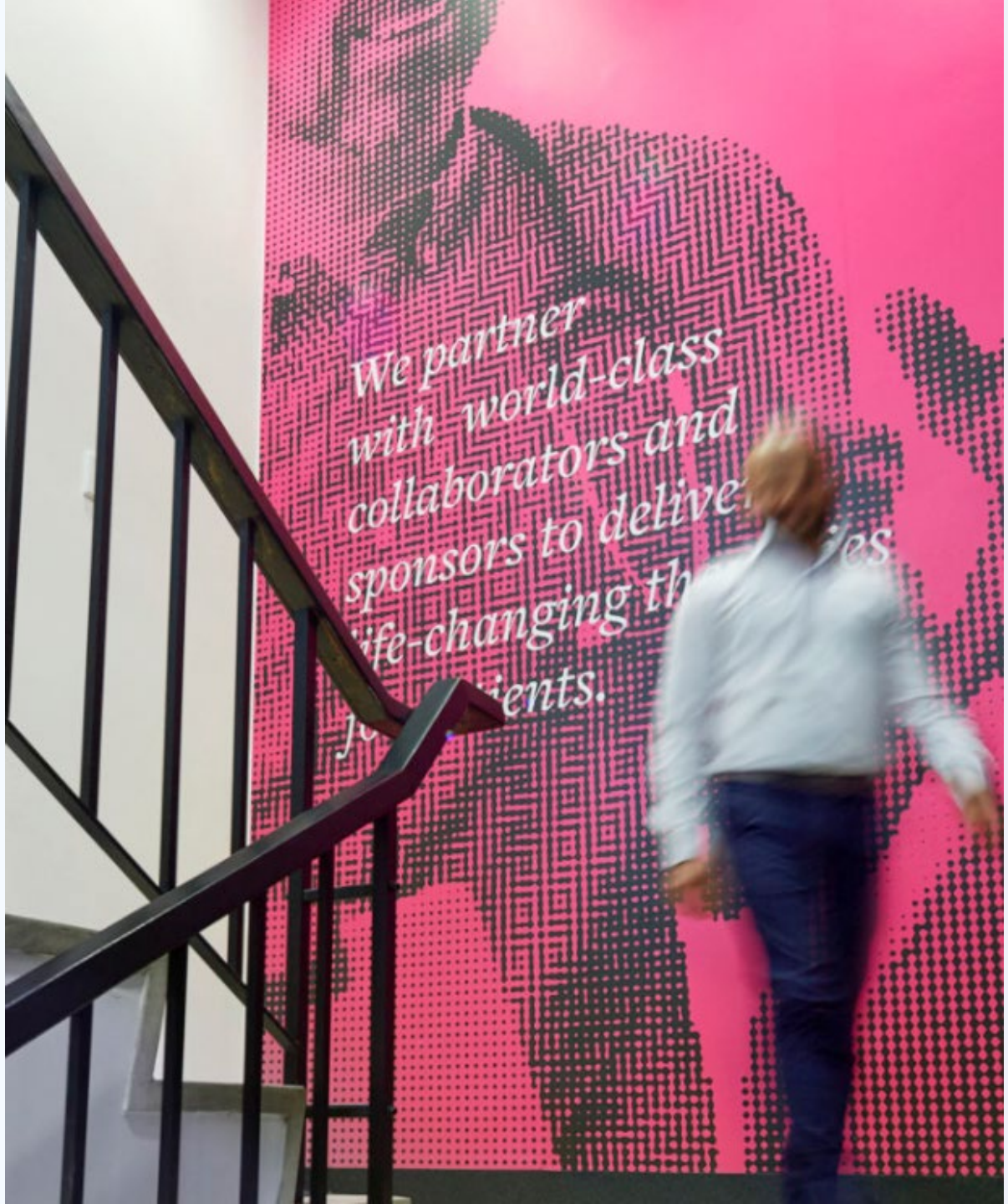
PHASE 3

Confirmation of efficacy and safety in comparison to existing medications in a large number of patients

REVIEW, REGULATORY APPROVAL & LAUNCH

ARG-007

Argenica is progressing through pre-clinical studies with IPO funding allowing the company to conduct its first Phase 1 clinical trial



linear

- Argenica has engaged world leading clinical research facility, Linear Clinical Research (Linear), who will begin the prework activities required for the **ARG-007** Phase 1 in-human clinical trial.
- Linear have a purpose built, state-of-the-art, clinical trial facility operating out of QEII Medical Centre in Perth, Western Australia that can support first in human (Phase 1) through to Phase 2 clinical trials.
- Linear have extensive experience in conducting healthy volunteer Phase 1 trials, including healthy volunteer and protocol designs.

ROADMAP TO PHASE 1 CLINICAL TRIAL

FINAL PHARMACOKINETIC STUDIES

ANIMAL STUDY

Determines how **ARG-007** is absorbed, distributed, and excreted by the body, and is essential for establishing dosing regimes for the Phase 1 clinical trial.

Q4 CY21 – EARLY Q1 CY22

SAFETY & TOXICOLOGY STUDIES

ANIMAL STUDY

Characterise the safety profile of **ARG-007** by identifying its impact on organ structure and / or functionality at a range of doses, including maximum tolerated dose.

Q4 CY21 – EARLY Q1 CY22

PRE-STUDY ACTIVITIES

Completion of preliminary study activities, including clinical site management setup, preparation of ethics submission.

Q4 CY21 – Q1 CY22

PHASE 1 CLINICAL TRIAL

IN-HUMAN STUDY

Ethics Approval, healthy volunteer recruitment, collection of safety data in a small number of healthy persons.

TRIAL BEGINS Q1 CY22

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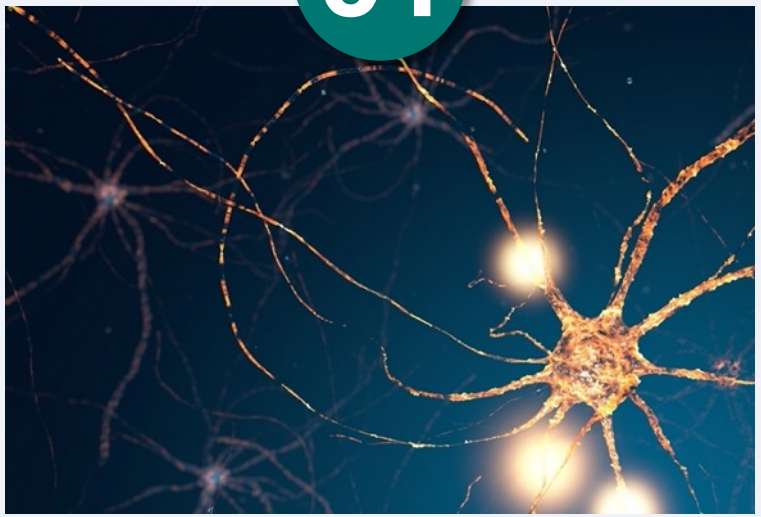


PRE-CLINICAL PHARMACOKINETIC STUDY

Pharmacokinetic (PK) studies are critical in determining how **ARG-007** is absorbed, distributed, metabolised, and excreted by the body and are essential for establishing appropriate dosing regimens for the Phase 1 trial.

Argenica recently announced **highly encouraging results** from its Pilot Pharmacokinetic study[1], including;

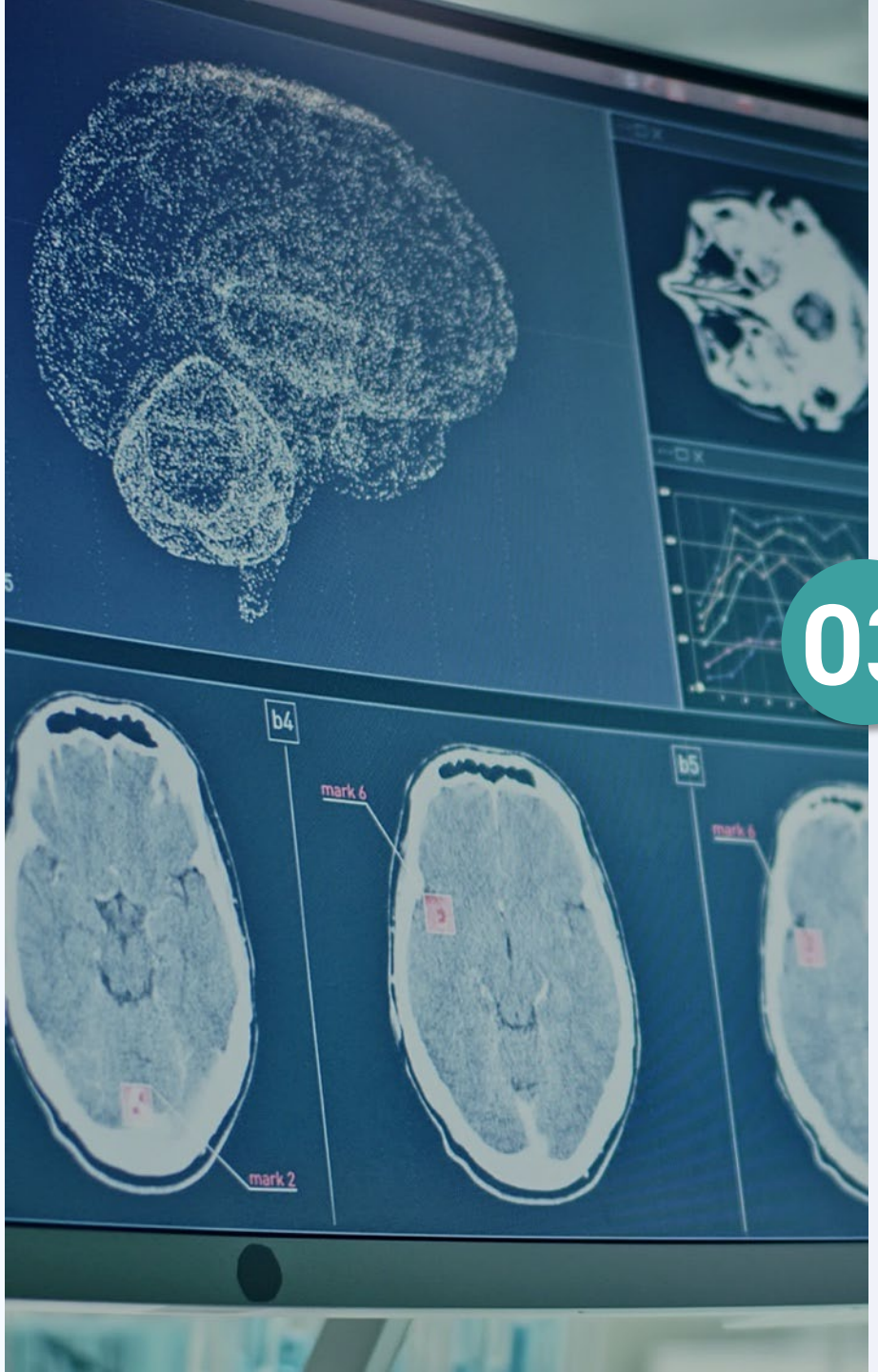
- Favorable PK profiles found in the dose range of 0.3-10 mg/kg which includes **ARG-007's** efficacious dose of approximately 1 mg/kg.
- **No adverse effects were observed**, indicating that **ARG-007** is potentially safe and well-tolerated at the relevant doses.

Confirmation of results from the full pharmacokinetics studies are expected throughout Q4 CY21 and into Q1 CY22.

(1) AGN ASX Release 'Argenica Completes Pilot Pre-Clinical Pharmacokinetics Study' 01/07/2021

PRE-CLINICAL SAFETY & TOXICOLOGY STUDY

- Safety and toxicology studies are **currently underway** to characterise the toxicity profile of **ARG-007** by identifying its impact on genes and target organs.
- These animal studies include assessment of the impact on genes, severity and reversibility of toxicity, as well as dose ranges and their relationship to exposure.
- By understanding the potential toxic effect on genes, kidneys, the heart, muscles, and other vital organs, toxicology studies help to determine the margin of safety of a drug for its expected clinical dose when administered to humans.
- The results from this study will be critical in guiding the parameters for Argenica's Phase 1 clinical trial to maximise safety and minimise risk.
- Results for genotoxicity, safety and toxicology studies are expected throughout Q4 CY21 and into Q1 CY22.



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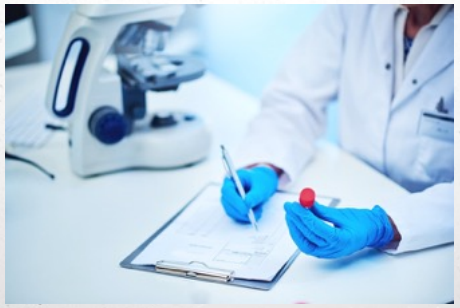
PHASE 1 CLINICAL TRIAL

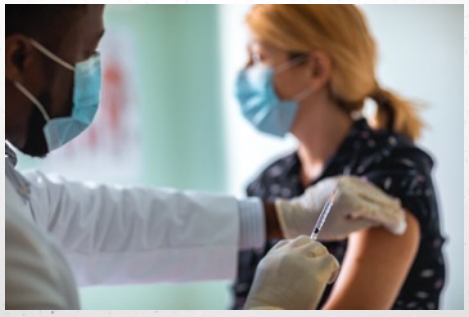
SAFETY & TOLERABILITY

Argenica's Phase 1 clinical trial will provide data surrounding the safety, tolerability and pharmacokinetics of **ARG-007** when administered in healthy human subjects.



DOSAGE & EFFECTS

The trial will investigate if the dose of **ARG-007** administered is safe, does not cause any adverse reactions and is well tolerated by healthy human subjects.



PHASE 1 OVERVIEW & OBJECTIVES

PROPOSED TRIAL DESIGN*

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.

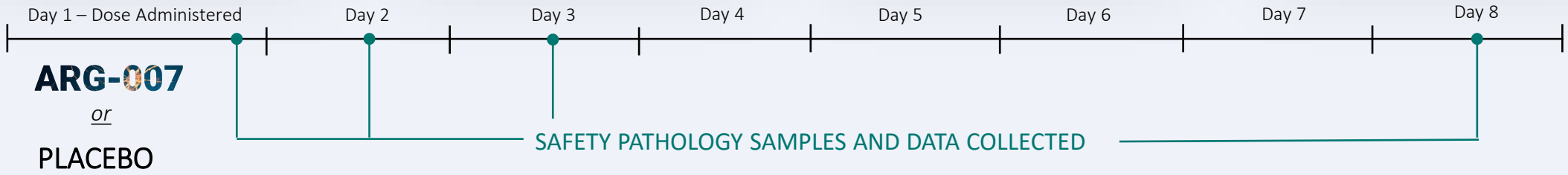
DURATION

Estimated 6 months, with preliminary findings expected following completion of volunteer dosing.

DESIGN

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

PROCEDURE OUTLINE FOR EACH PARTICIPANT



**the trial design is subject to approval by a Human Research Ethics Committee (HREC). Trial design documentation and preclinical safety and toxicology data will be submitted to a HREC in Q1 CY22.*

Study parameters are subject to change and should only be considered as a guide

PRIMARY OBJECTIVES OF PHASE 1

1. IMPROVE THE **UNDERSTANDING** OF WHAT THE BODY DOES TO **ARG-007**

2. EVALUATE THE **SAFETY OF ARG-007** WHEN ADMINISTERED

3. DETERMINE THE **IDEAL SAFE DOSAGE**

4. IDENTIFY ANY POSSIBLE **ADVERSE REACTIONS**

PHASE 2 STUDIES

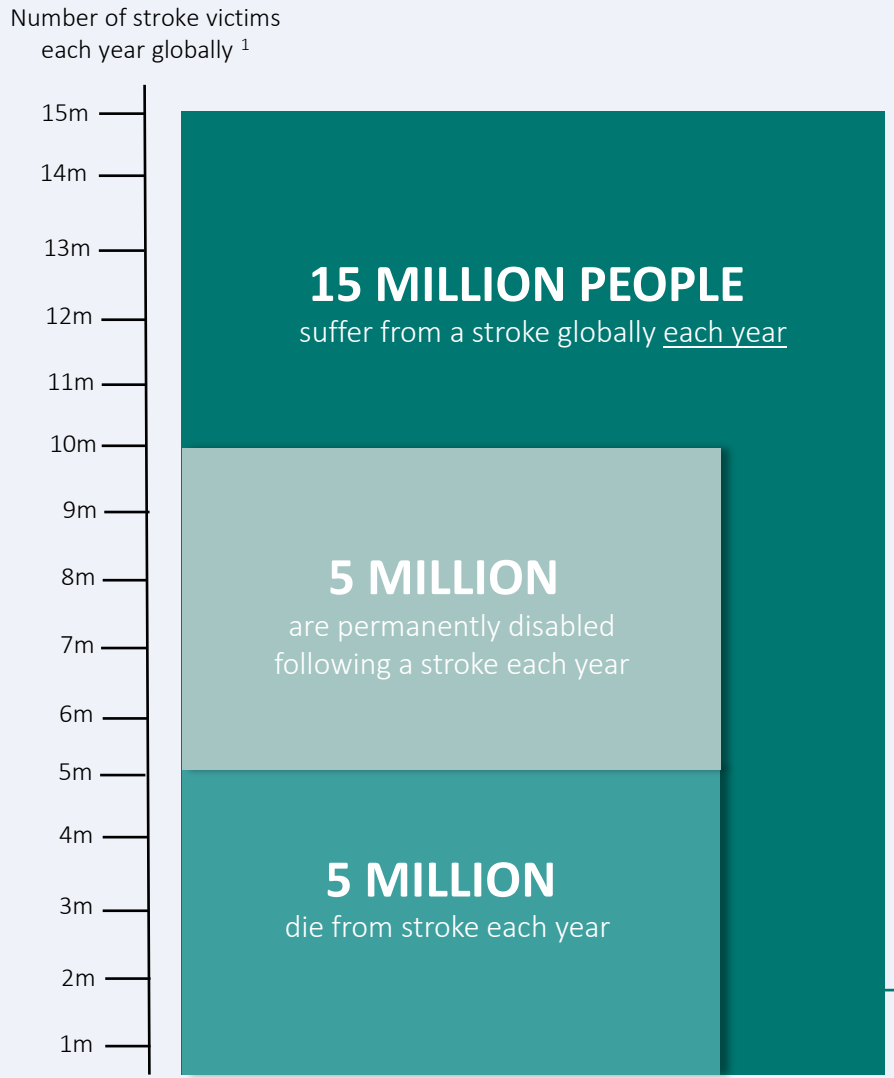
Data collected from the Phase 1 clinical trial will be critical to progress into Phase 2 trials, where **ARG-007** will be administered to stroke patients.

OTHER INDICATIONS

While stroke is the current commercial focus, safety data from the Phase 1 clinical trial can potentially be used to accelerate the clinical development of **ARG-007** in other types of brain injuries, including;

- **Perinatal hypoxic ischemic encephalopathy (HIE)** - A type of brain dysfunction that occurs in neonates when the brain doesn't receive enough oxygen or blood flow for a period of time.
- **Traumatic brain injury (TBI) & concussion** - An injury resulting from a violent blow or jolt to the head or body.
- **Surgically induced stroke** – Including stokes sustained during endovascular aneurysm repair and transcatheter aortic valve implantation.

THE OPPORTUNITY IN STROKE



UNTAPPED OPPORTUNITY

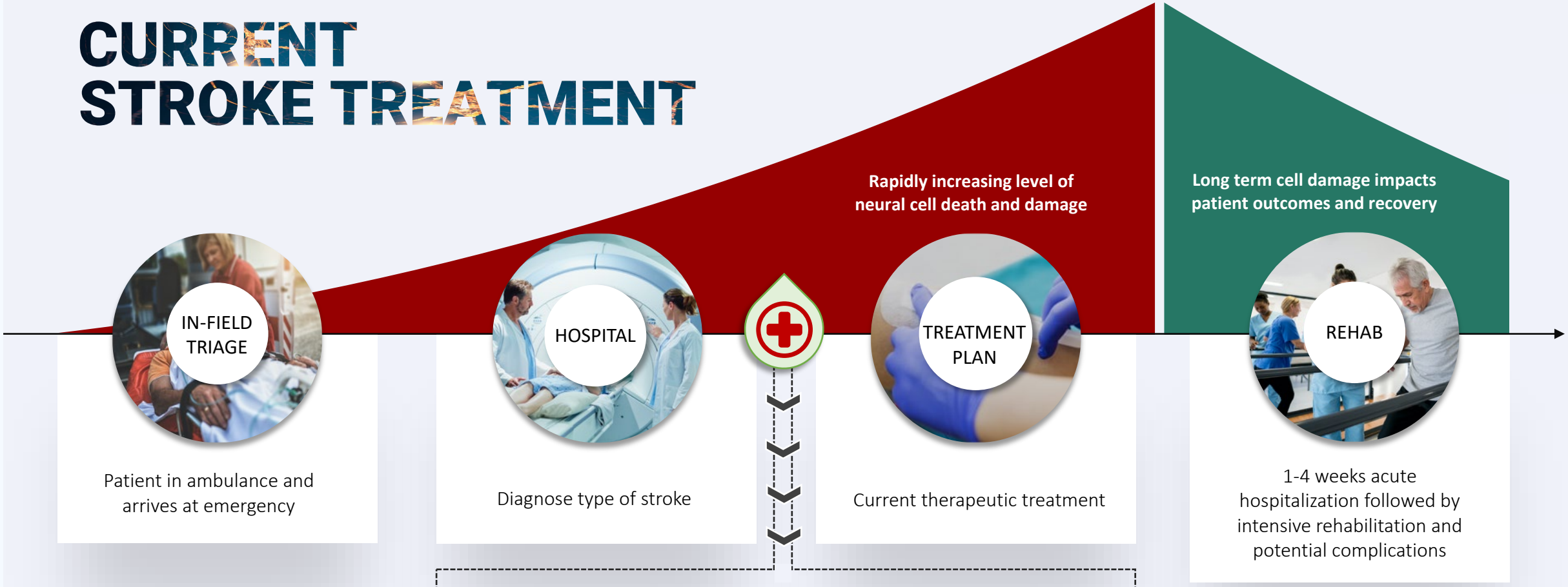
- The estimated cost to treat stroke is expected to be **$183 Billion by 2030** [2]
- Current standard of care in global markets caters to the treatment and diagnosis of stroke, not the protection of brain cells.
- Timely diagnosis and treatment is critical after a stroke as the brain ages approximately 3.6 years every hour that appropriate treatment is delayed[1].
- Significant global research efforts are currently underway to find therapeutic agents that can address brain tissue damage following stroke, however there are no universally available drugs that protect brain cells following stroke.
- Argenica's vision is to **develop and commercialise** therapeutics which could potentially help the 15 million stroke victims by protecting brain tissue against damage during a stroke.

1. World Health Organisationhttps. Accessed 3 May 2021 <www.who.int/cardiovascular_diseases/en/cvd_atlas_15_burden_stroke.pdf>

2. Gorelick PB. "The global burden of stroke: persistent and disabling". Lancet Neurol. 2019 May;18(5):417-418.

Cautionary Note: *Access to markets is subject to the Company being able to successfully develop and commercialise ARG-007. As with any entity seeking to enter into a global marketplace, any product developed by Argenica will have applications that are constrained by market segment, relevant regulations, industrial application, geographical barriers and intellectual property rights.*

CURRENT STROKE TREATMENT



Patient in ambulance and arrives at emergency

Diagnose type of stroke

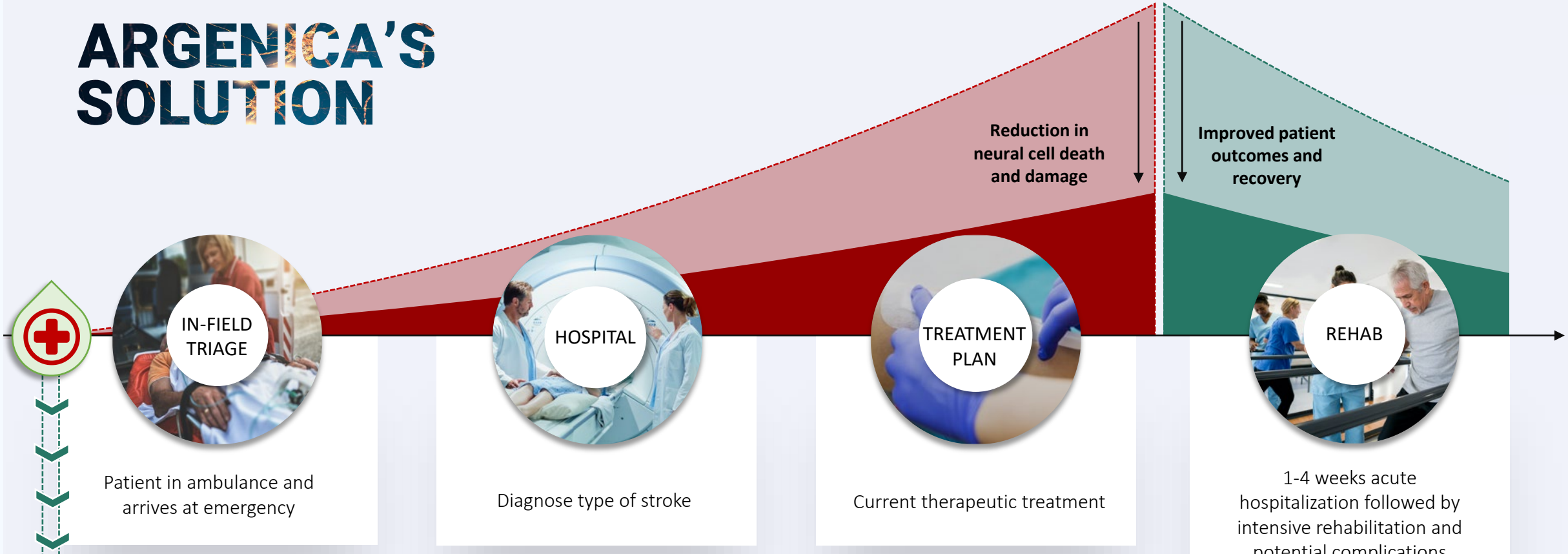
Current therapeutic treatment

1-4 weeks acute hospitalization followed by intensive rehabilitation and potential complications

Current therapeutic treatments are administrated <u>after</u> imaging diagnosis and are different for each stroke type;

- Treatment interventions occur many hours after the initial stroke
- Do not prevent or reverse further neuronal damage and cell death

ARGENICA'S SOLUTION



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Diagnose type of stroke

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ARGENICA THERAPEUTIC TREATMENT

Immediate or point of care intervention with neuroprotective therapeutic **ARG-007** could significantly impact patient recovery and long-term prognosis by reducing penumbral cell death

- Reduce brain cell death during period prior to formal diagnosis and treatment of underlying stroke condition
- Small change in infarct volume or cell death can have very significant impact on patient life and functional outcomes

ARG-007
NEUROPROTECTION IN STROKE

ARG-007, a Cationic Arginine Rich Peptide (CARP), is Argenica's leading candidate to protect brain tissue against damage during a stroke and to enhance the recovery once a stroke has taken place.

SAFE & EARLY INTERVENTION

Safe, regardless of the underlying cause of stroke, with the potential to bypass the need for time consuming diagnostic procedures that precede conventional treatment.

MINIMISE INJURY

Reduces ischemia and preserves still viable tissue, immediately protects neurons from glucose stress and oxygen deprivation.

IMPROVE OUTCOMES

Reduce hospitalisation time, special care requirements and intensive rehabilitation time. Increase likelihood of preserving functional recovery.

** These are assumptions based on the potential benefits Argenica could have on patients and the healthcare system if successfully commercialised*

For further information please contact:

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