PHASE 2 STROKE CLINICAL TRIAL UPDATE: PATIENT DOSING ON TRACK TO COMMENCE Q1 CY2024

Highlights:

- *The manufacturing of the ARG-007 drug substance required for the Phase 2 clinical trial has now been completed, with the finalised sterile drug product manufacturing to be completed by the end of Q4 CY2023. The completion of the manufacturing of the clinical trial batch of ARG-007 ensures Argenica can commence first patient dosing in Q1 CY2024.*

- *Final approvals for Hospital clinical trial sites remains on-track, with one hospital ready to commence patient dosing, and several others in the final stages of approval.*

- *Independent Data Safety Monitoring Board (DSMB) established, ready for the commencement of the Phase 2 trial.*

- *The Phase 2 trial will provide data on the safety and preliminary efficacy of ARG-007 in acute ischaemic stroke patients, paving the way for a pivotal Phase 3 trial and potential partnering with pharmaceutical companies.*

Perth, Australia; 14 December 2023 - Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke, is pleased to provide an update on the progress of the Company's Phase 2 clinical trial in acute ischaemic stroke (AIS) patients.

MANUFACTURING

Melbourne based peptide manufacturer, Auspep Clinical Peptides, has completed the manufacturing of the ARG-007 drug substance (in powder form). This has since been sent to, and received by, Argenica's European based contract manufacturer, CordenPharma, to be fill and finished as sterilised vials of the ARG-007 drug product solution under Good Manufacturing Practices (GMP) ready for dosing of patients in the Phase 2 clinical trial.

CordenPharma has successfully completed the scale up of its manufacturing processes and is now able to manufacture ARG-007 under GMP conditions to produce the finalised sterile vials

of ARG-007, the drug product that will be used in the Phase 2 trial. The manufacturing of saline placebo vials has already been completed.

Release testing (testing concentration, consistency, etc.) of the vials is expected to be completed early in Q1 2024, following which, vials of ARG-007 and placebo will be shipped to Central Pharmacy Logistics (CPL) in Australia. CPL will then log all vials and distribute them to each hospital site, ready for patient dosing in Q1 2024.

CLINICAL TRIAL SITES SET UP

Since receiving ethics approval in September 2023, Argenica's clinical trial team has been working with a number of hospitals across Australia to establish them as clinical trial sites for the Phase 2 clinical trial.

Whilst the trial has ethics approval, each hospital participating in the Phase 2 clinical trial is accountable for the scientific quality, ethical acceptability and safety of the clinical trial it conducts within the hospital. Therefore, Argenica has been working diligently with each hospital through a site-specific assessment (SSA) process which forms good research governance and is an essential component for the responsible conduct of research.

Currently Royal Melbourne, Princess Alexandra and John Hunter hospitals have submitted SSA research governance documentation to their respective Research Governance Offices seeking approval to undertake the Phase 2 trial of ARG-007 in AIS patients. Royal Melbourne Hospital is the first to have received research governance approval, allowing patient recruitment and dosing to commence once vials of ARG-007 and placebo are received.

We anticipate SSA research governance documentation to be submitted in December at Sir Charles Gardiner Hospital (Perth), Royal Adelaide Hospital (Adelaide) and Liverpool Hospital (Sydney). The additional four hospitals will complete SSA research governance in January 2024.

Once SSAs have been approved in each hospital by their respective Research Governance Offices, they may commence dosing patients under the approved Phase 2 clinical trial protocol[1].

DATA SAFETY MONITORING BOARD

As part of the Phase 2 trial, Argenica has established an independent Data Safety Monitoring Board (DSMB) comprising a number of independent neurologists and a biostatistician, who will be responsible for reviewing the safety data as the trial progresses. The DSMB will be supported by an unblinded project manager and statistician.

[1] https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=385922&isReview=true

The purpose of the DSMB is to monitor the rates of adverse events (AEs), endpoints, and study progress in the Phase 2 trial. In addition, the DSMB will provide recommendations regarding the continuation, modification, or termination of the study to Argenica and will practice due diligence to ensure, given all available information, that subsequent subjects are not placed at any undue risk.

During the trial, there will be five planned data review meetings with the DSMB. The primary purpose of the data review meeting is to allow the DSMB to review and discuss the safety data outputs in order to make recommendations on whether any variations to the study protocol may be required and to confirm that the study can continue. The outcomes of these meetings will be made available to the market.

The first data review meeting will occur after 5 subjects have been randomized in the trial. Subsequent meetings will then be held at least every six months, subject to quarterly recruitment rates being achieved (i.e 25%, 50%, 75%). The first data review meeting will be blinded. Trial enrolment will not be halted during planned DSMB review of safety data.

Dr Liz Dallimore, Managing Director, stated "*Proving the scale-up manufacturing of the clinical grade ARG-007 drug product is a significant milestone for the Company, and we are delighted manufacturing timelines remain on track. Further, we are pleased with the progress of research governance at each hospital, there is a lot of work going on behind the scenes in the Company to prepare for our upcoming Phase 2 trial. We look forward to keeping shareholders updated as further milestones are achieved*."

PHASE 2 STROKE CLINICAL TRIAL OVERVIEW

The Phase 2 trial will be a Multicenter, Double-Blinded, Randomized, Placebo-Controlled, Parallel-Group, Single-Dose Study to Determine the Safety, Preliminary Efficacy, and Pharmacokinetics of ARG-007 in Acute Ischemic Stroke Patients (SEANCON).

The trial is designed to test how safe ARG-007 is in acute ischaemic stroke (AIS) patients, with safety being a significant regulatory hurdle in drug development. Proving ARG-007 is safe in AIS patients will pave the way for Argenica to progress to a pivotal Phase 3 trial and engage with global pharmaceutical companies.

Furthermore, the trial is designed to generate preliminary data on the ability of ARG-007 to reduce brain tissue death following stroke and mechanical removal of brain clot (thrombectomy). Proving the neuroprotective ability of ARG-007 will be a significant de-risking milestone for the Company and place Argenica at the forefront of neuroprotective clinical validation.

The trial will recruit only patients with a diagnosed large vessel occlusion (LVO) stroke that are eligible for endovascular thrombectomy (mechanical removal of a clot in the brain) will be eligible to be enrolled in the trial. By narrowing the patient selection to LVO strokes

receiving endovascular thrombectomy only, it will ensure the trial has improved control for end point evaluation to power a successful outcome. LVO strokes account for close to 40% of all acute ischaemic strokes, however, are responsible for 60% of post-stroke dependency and 90% of mortalities after stroke, and therefore are considered the most devastating type of stroke[2].

The trial will be conducted in up to 10 hospitals across Australia that have dedicated stroke care units capable of performing endovascular thrombectomy. As patients enter the emergency department with a suspected AIS, they will be assessed for eligibility to participate in the trial by the principal investigator (PI) neurologist at each trial site. Following confirmation of a LVO stroke via imaging and the clinical decision to treat with endovascular thrombectomy, eligible patients will be enrolled on the trial. Enrolled patients will be randomly assigned to receive either an intravenously (IV) delivered dose of ARG-007 or an IV delivered saline placebo, to be administered prior to completion of endovascular thrombectomy procedure. The trial will be blinded, meaning neither the patient nor the hospital staff will know whether the patient has received ARG-007 or a placebo.

Following treatment, patients will be assessed for key safety outcomes as well as infarct volume and functional outcomes via a number of standard assessments.

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

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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.

[2] Malhotra K, Gornbein J, Saver JL. Ischemic Strokes Due to Large-Vessel Occlusions Contribute Disproportionately to Stroke-Related Dependence and Death: A Review. Front Neurol. 2017 Nov 30;8:651.