ARG-007 PHASE 2 MANUFACTURING COMPLETED WITH THE CLINICAL TRIAL ON TRACK TO COMMENCE DOSING IN MARCH 2024

Highlights:

- *Manufacturing and release testing of GMP grade ARG-007 drug product has been successfully completed, ready for patient dosing in the upcoming Phase 2 clinical trial.*

- *Gold Coast Hospital and Royal Brisbane & Women's Hospital have now been included as trial sites, now confirming the ten clinical trial sites to be involved in dosing stroke patients in the Phase 2 trial.*

- *Site initiation visits will commence in February, enabling clinical trial sites to be ready to start recruiting and dosing patients into the trial.*

- *Dosing of first patients in the Phase 2 trial is on track to commence in March 2024.*

Perth, Australia; 12 February 2024 - 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 its Phase 2 trial in acute ischaemic stroke (AIS) patients.

GMP Manufacturing

CordenPharma has confirmed the successful completion of manufacturing of the clinical trial batch of ARG-007 under GMP conditions, producing the finalised sterile vials of ARG-007 for use in the Phase 2 trial. Extensive testing of the clinical trial batch of both the ARG-007 drug product and placebo vials has now been completed and both have now been approved for release.

The ARG-007 drug product and saline placebo will arrive at clinical trial sites across Australia in February, **ready for patient dosing in March 2024.**

Clinical Trial Sites

Argenica continues to work with its trial sites across Australia and has now added Gold Coast and Royal Brisbane & Women's Hospitals in Queensland as clinical trial sites. Both hospitals have extensive experience in undertaking stroke clinical trials. Sunshine Hospital in Melbourne has been removed as a trial site due to logistical challenges identified in transporting patients from the facility into a thrombectomy centre in Melbourne.

The final hospital sites to be involved in the trial includes Sir Charles Gairdner Hospital, Fiona Stanley Hospital, Royal Melbourne Hospital, Monash Health, Princess Alexandra Hospital, Gold Coast Hospital, John Hunter Hospital, Royal Adelaide Hospital, Royal Brisbane & Women's Hospital, and Liverpool Hospital.

All trial sites are comprehensive stroke units with highly specialised resources and personnel available (nine of the ten hospitals provide thrombectomy services for large vessel occlusion AIS patients 24 hours a day, seven days a week, with one hospital, being the Fiona Stanley Hospital, providing this service during the day only). All trial sites are located in large population areas and see high volumes of stroke patients, including the most complex presentations such as large vessel occlusions.

Five of the ten hospitals have now also completed site-specific assessment (SSA) research governance requirements for the trial, these being Royal Melbourne Hospital, Princess Alexandra Hospital, John Hunter Hospital, Royal Adelaide Hospital, and Liverpool Hospital. These sites will shortly be activated through site initiation visits, allowing patient dosing to commence. The remaining five hospitals will complete SSA research governance in March and be activated shortly after. Accordingly, **dosing of the first patients in the trial is expected in March.**

After the first five patients are dosed, the independent Data Safety Monitoring Board (DSMB) will meet to assess the safety data of these patients and to provide a recommendation on the continuation of the trial under the current study protocol. Follow up DSMB meetings will then be held following the first 23 patients dosed, then the subsequent 23 patients dosed, and so on up until the total cohort of 92 patients have been dosed. Argenica will report on the outcomes of the safety assessment and patient recruitment status following each DSMB meeting.

Dr Liz Dallimore, **Argenica's Managing Director**, stated "*Achieving successful scale up the GMP manufacturing of ARG-007 for our upcoming Phase 2 trial is a huge milestone for the Company. We're also delighted to bring on the Gold Coast and Royal Brisbane & Women's hospitals into the trial. Both will be fantastic additions to the trial, with both having exceptional experience in stroke care and clinical trials. We look forward to working with such highly credentialled and committed professionals at all of our trial sites in the delivery of this Phase 2 trial".*

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 primary endpoint is to test the safety of ARG-007 in acute ischaemic stroke (AIS) patients, with safety being a significant regulatory hurdle in drug development in this therapeutic field. Proving ARG-007 is safe in AIS patients is a significant milestone in stroke clinical development and will pave the way for Argenica to progress towards a pivotal Phase 3 trial.

Importantly, the trial is also designed to generate preliminary signals of efficacy on the ability of ARG-007 to reduce brain tissue death following stroke and endovascular thrombectomy. Providing evidence of the neuroprotective ability of ARG-007 to help reduce the total volume of brain cell death (infarct volume) by preserving neurons would place ARG-007 as a leading neuroprotective drug candidate and mark a significant clinical validation milestone for Argenica.

The trial will recruit only patients with a diagnosed large vessel occlusion (LVO) stroke that are eligible for endovascular thrombectomy. By narrowing the patient selection to only LVO strokes receiving endovascular thrombectomy, it will provide the opportunity for Argenica to assess the ability of ARG-007 to not only work on brain injury caused by the clot blockage, but also protecting against the secondary injury caused to brain cells following clot removal. This secondary injury, or reperfusion injury, is the result of the rapid restoration of bloody supply to the brain tissue after a period of ischaemia. LVO strokes account for close to 40% of all acute ischaemic strokes, however they are responsible for 60% of post-stroke dependency and 90% of mortalities after stroke, and therefore are considered the most devastating type of stroke[1].

The trial will be conducted in 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.

[1] 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.

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

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.