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ASX Release

INTERIM STAGE 2 ANALYSIS CONFIRMS HYPERACUTE AND ACUTE ISCHAEMIC STROKE DETECTION CAPABILITIES

Highlights:

- *Stage 2 interim data analysis confirms positive AI algorithm performance to help answer the clinical question of ischaemia or not ('clot or not') (see chart on next page).*
- *The AI algorithm displays an encouraging ability to identify patterns and features across complex ischaemic patient data sets, including early onset hyperacute ischaemic stroke which is often challenging to detect on non-contrast computed tomography (NCCT).*
- *This analysis follows encouraging interim data analysis which confirmed strong AI model performance in answering haemorrhage or not ('blood or not')*[1]
- *Patient recruitment for the final Stage 3 of Pre-Validation clinical trial is on track to complete in the coming months with over half the target cohort (up to 30 haemorrhages) recruited to date.*
- *The neuro-diagnostic capabilities observed in interim cross validation analysis of Stage 2 data illustrates the disruptive potential of EMVision's technology to significantly improve the diagnosis, care, and outcomes of both haemorrhagic and ischaemic stroke patients.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to share further positive interim analysis from the latest phase of its clinical trials. These multi-site clinical trials are focused on advancing EMVision's neurodiagnostic AI algorithms to aid in the diagnosis of suspected haemorrhagic or ischaemic stroke.

In Stage 2 of the pre-validation trial, a total of 180 patients were enrolled. Patients presented to the emergency department with stroke-like symptoms, across the three trial sites: Liverpool Hospital, Royal Melbourne and Princess Alexandra Hospital Brisbane. 75 patients had confirmed ischaemic strokes and 105 non-ischaemia cases (including 18 haemorrhagic strokes (caused by bleeding due to a ruptured blood vessel)), 67 stroke mimics and 20 transient ischaemic attacks (TIA).

The Alberta Stroke Program Early CT Score (ASPECTS) was used to measure the extent of brain damage in the ischaemic stroke patients by quantifying early ischaemic changes detected on brain CT scans. The ASPECTS score ranges from 0 to 10, with lower scores indicating more regions of the brain are affected, resulting in more severe brain damage. Scores below 7 are associated with worse functional outcomes for patients. In Stage 2 of the current trial, the average ASPECTS score for the ischaemic stroke cohort was 7.4, representing a diverse range of stroke cases enrolled.

[1] ASX Release 27 March 2024

Confidently Diagnosing Ischaemia

For patients suspected of having an acute ischaemic stroke, the American Heart Association recommends brain imaging and neuro-diagnosis should be performed as quickly as possible. In most cases, this initially involves non-contrast computed tomography (NCCT) scan. Rapid imaging is critical for patients who may benefit from treatments such as IV alteplase (clot-busting drugs) and/or mechanical thrombectomy (clot retrieval). NCCT brain scans rule out / exclude haemorrhage ('blood or not') in patients with clinical signs of stroke, which is essential when considering thrombolysis treatment (clot-busting).

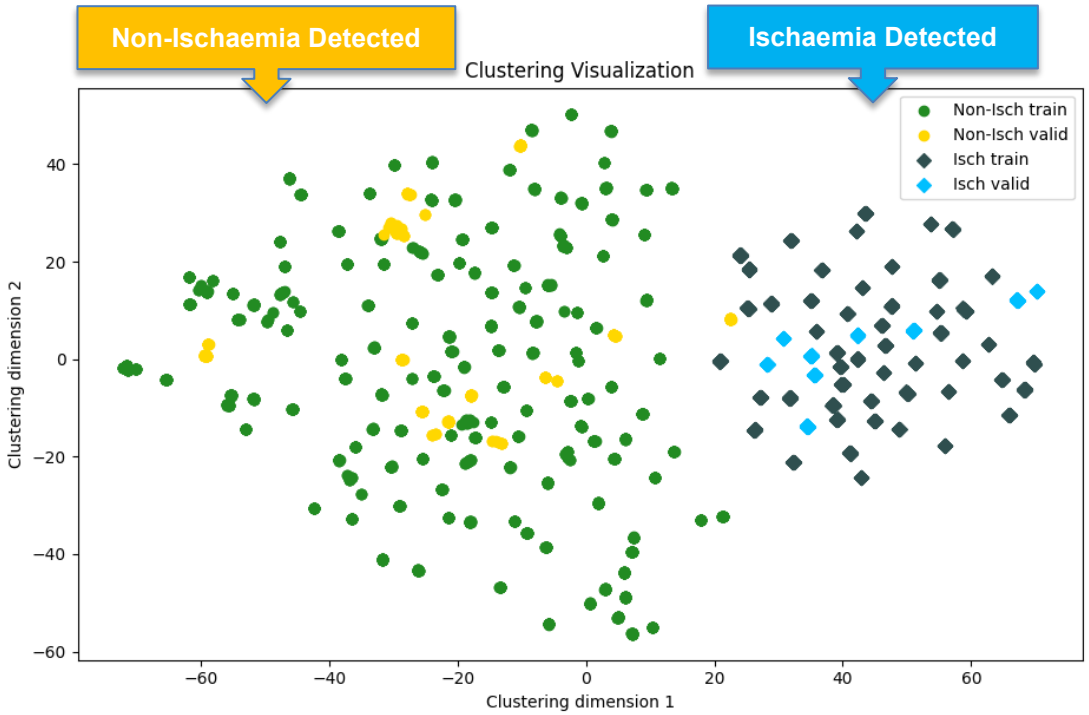
The literature on NCCT shows a limited sensitivity to detecting acute ischaemia. For patients with suspected ischemic stroke, advanced imaging modalities such as CT Angiogram, CT Perfusion or MRI are often used to confirm the presence of ischaemia ('clot or not') and determine a patient's eligibility for thrombectomy (clot retrieval). Depending on the neuro-diagnosis, and treatment capabilities of the hospital to perform urgent intervention, a time critical decision is whether to transfer the patient to a comprehensive stroke centre, or not. The urgency of stroke care underscores the need for accurate and timely tools to aid its diagnosis.

EMVision's encouraging AI algorithm performance with the AI model answering the critical clinical question in acute stroke diagnosis – ***"Is it a haemorrhage or not?"*** ('blood or not') was previously reported in the ASX announcement on 27th March 2024 ('Stage 2 insights confirm diagnostic and clinical viability'). EMVision now presents interim analysis which confirms positive AI algorithm capability to also detect the presence of ischemia to help answer the clinical question – "***Is it ischaemia or not"*** ('clot or not').

New Interim Analysis

Data from Stage 2 is being used to enhance AI algorithms, per protocol. Cross validation interim analysis has been undertaken to prepare for the upcoming Validation (sensitivity/specificity confirmation) trial. Cross validation (below, 'ischemia or not,' Stage 2 data) is a statistical method for evaluating AI algorithms by randomly dividing data into multiple subsets: in each iteration, a subset is used to validate the model on unseen data, while the remaining subsets are used to train the model.

The detection and classification performance of the AI algorithm can then be estimated by observing the clustering that occurs in the cross validation data. The ideal clustering being ischemic and non-ischemic cases are distinctly separate.



Clustering shows validation cases of confirmed ischaemia (blue) and non-ischaemia (orange) as distinctly separate, demonstrating the AI algorithm's ability to identify and classify ischaemic stroke from non-ischaemia.

The AI model demonstrates an encouraging ability to identify patterns and features in the signals across complex ischaemic patient data sets, including cases of very early onset hyperacute ischaemic stroke where there are no or minimal non-diagnostic radiological findings on traditional CT (NCCT). The mean time from onset for the Validation ischaemia cases was 7.5 hours (range 1.52 to 20.55). Cross validation is used in the development and algorithm training phase and directing continuing refinement. The determination of diagnostic sensitivity and specificity will be made after development completion and when the upcoming Validation clinical trial is concluded.

The neurodiagnostic capabilities shown in this interim cross validation analysis across Stage 2 data continue to demonstrate the potential of the EMVision technology to significantly improve the diagnosis, care, and outcomes for both haemorrhagic and ischaemic stroke patients, from early at the patient presentation, including prioritised care of hyperacute/acute strokes (as opposed to stroke mimics), at the point-of-care.

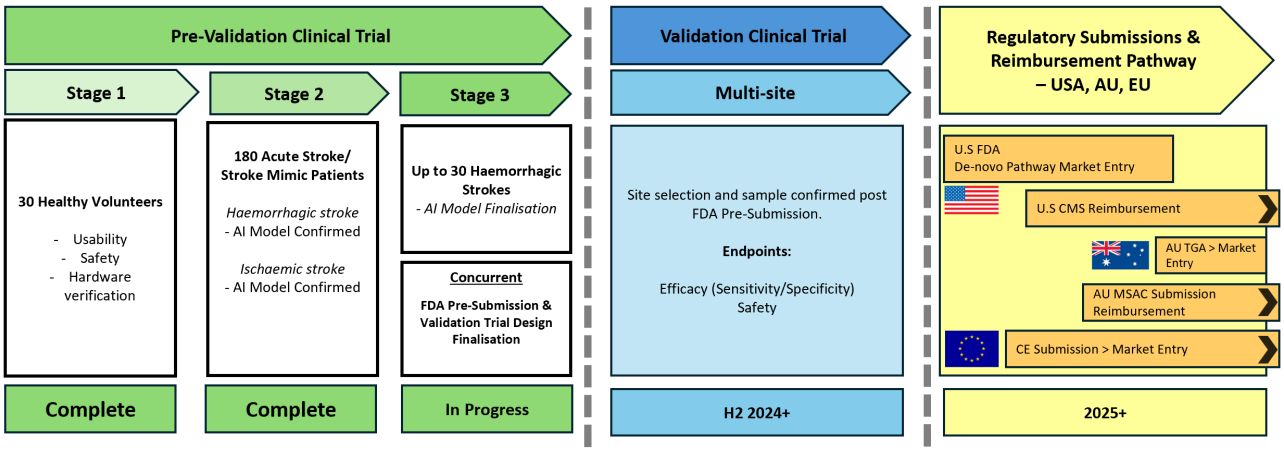
Principal investigator at Royal Melbourne Hospital Dr Angela Dos Santos commented "The positive interim results for ischaemia detection, considered alongside those previously for haemorrhage detection, illustrate the technology's evolving capability in addressing 2 of the most pressing questions at acute suspected stroke presentation: is there a stroke, and if so is it haemorrhagic or ischaemic? Timely answering of these questions allow the most effective care pathway to be activated as early as possible."

Principal investigator at Liverpool Hospital Dr Dennis Cortado commented "The latest advancement in this novel technology demonstrates its unique position within neurodiagnostic tools. The ability to indicate likely haemorrhagic or ischaemic stroke, in an accessible and easy to use technology, is not generally available today. As the clinical trial and device development progresses, we look forward to seeing how this device will expand our neurodiagnostic capabilities."

EMVision CEO Scott Kirkland commented, "The ability of our technology to also detect hyperacute and acute ischaemic cases in this cross validation interim analysis is incredibly exciting for our team, our clinical collaborators, and most importantly, what this may mean for the improvement of care pathways and outcomes for future stroke patients."

Stage 3 Progress

Patient recruitment for the final Stage 3 of Pre-Validation clinical trial is well on track to complete in the coming months with over half the target cohort (up to 30 haemorrhages) recruited to date. See clinical, regulatory and reimbursement roadmap below.



This roadmap is indicative only and subject to change.

Authorised for release by the Board of the Company.

[ENDS]

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Clinical Investigations Roadmap

The sites have been activated progressively, commencing with Liverpool Hospital. All sites that have been selected are major stroke centres that treat significant volumes of stroke patients each year.

TITLE	'EMVIEW' EMVision Gen 1 Brain Scanner Study on Acute Stroke Participants
DEVICE DESCRIPTION	The EMVision Brain Scanner is a device system which obtains images of human brain using electromagnetic (microwave) techniques.
STUDY SITES	**Site 1** - Liverpool Hospital **Site 2** - Royal Melbourne Hospital **Site 3** - Princess Alexandra Hospital Additional site to be added and activated as required
PARTICIPANTS	Presenting to Emergency Department with suspected stroke
PATIENT COHORT	***Pre-validation Phase*** **Stage 1:** 30 Healthy participants **Stage 2:** Up to 150 Acute stroke/stroke mimic participants **Stage 3:** Up to 30 bleeds Regulatory Body Engagement ***Validation Phase*** Endpoint and sample size will be confirmed during the pre-validation phase
ENDPOINTS	• Hardware verification • Safety • Stroke mimic and acute stroke data to enhance AI algorithms • Efficacy (sensitivity/specificity) • Safety
DURATION & REPORTING	**Anticipated to be 12+ months. The Company expects to provide updates to the market as it reaches relevant milestones throughout the clinical testing**
INCLUSION CRITERIA	Adults ≥ 18 years of age. Presenting to hospital with acute neurological deficit suspect to be stroke and within 24 hours of symptom onset. The use of the EMV Brain Scanner will not delay the treatment of the participant. CT brain imaging following clinical evaluation in Emergency Department per standard of care. Ability to provide informed consent. Participants will provide written informed consent. Where this is not possible, consent from a legal authorized representative will be obtained. Head size deemed suitable for scanning with the EMVision Brain Scanner.
EXCLUSION CRITERIA	Has received treatment for current (suspected) stroke event prior to initial CT scan AND EMVision Brain Scanner scan. Pregnant or breastfeeding. Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography. Presence of any implanted electro-stimulating devices in the head and neck. Presence of any large metallic craniofacial implants, such as bone fixation plates, mesh etc. (Note that small metallic objects, such an aneurysm coils etc., are acceptable) Presence of an intracranial pressure monitor or any other similar sensor that may compromise the placement of the investigational device Inability to wear the investigational device (skin lesions on scalp, previous intracranial surgeries etc.). Unable to lie still for the duration of the scan. Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
SCANNING PROCESS FOR A TYPICAL STROKE PATIENT	**Admission** — Emergency Department — CT + EMV Scans **+24 Hours** — Radiology / In-ward — CT and/or MRI + EMV Scans **3-5 Days later** — Radiology / In-ward — CT and/or MRI + EMV Scans

About EMVision Medical Devices

EMVision Medical Devices Limited (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neuroimaging devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane www.emvisionmedical.com

Forward-looking Statements

This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of EMVision and certain of the plans and objectives of EMVision with respect to these items. These forward-looking statements are not historical facts but rather are based on EMVision's current expectations, estimates and projections about the industry in which EMVision operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of EMVision, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. EMVision cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of EMVision only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. EMVision will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

Inherent risks of Investment in Medical Device development Companies

There are a number of inherent risks associated with the development of new medical device products to a marketable stage. The clinical trial process, which is often lengthy, is designed to assess the safety and efficacy of a device prior to commercialisation and there is no guarantee of achieving the outcomes necessary to generate a viable commercial product. Other risks include uncertainty of patent protection and proprietary rights, the obtaining of necessary regulatory authority approvals and the evolving competitive landscape. Companies such as EMVision are dependent on the success of their research and development projects, product development and on the ability to attract funding to support these activities. Investment in research and development and novel product development cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore investment in Companies specialising in such development must be regarded as speculative. EMVision recommends that professional investment advice be sought prior to such investments and cautions investors that the risks of an investment in an entity such as EMVision is not limited to the risks disclosed in this announcement.