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ASX Release

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UCLA HEALTH PIVOTAL TRIAL ACTIVATION AND CONTINUOUS INNOVATION STUDY UPDATE

Key Highlights:

- **Premier stroke research hub UCLA Health is scheduled for site activation in two weeks with emu™ brain scanner now shipped.**
- **Pivotal Trial Steering Committee (TSC) assembled, comprised of international Key Opinion Leaders in stroke.**
- **EMVision remains on track with study operations required for De Novo submission, with the Pivotal Trial recruitment target expected to be achieved during CY H1 2026 – in line with prior guidance.**
- **New site, Box Hill Hospital, added to Continuous Innovation Study.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide the following update on the Pivotal (Validation) Trial and Continuous Innovation Study for the emu™ brain scanner device.

Sixth and Final Pivotal Trial Site, UCLA Health, Activation in Progess

The impending activation at UCLA Health completes site initiations for the Pivotal Trial. UCLA Health is a leading U.S. academic health system and stroke centre, providing world-class patient care and advancing medical research and education. UCLA Health serves as a major referral centre for complex neurological and cerebrovascular care. The UCLA site is led by Principal Investigator Dr May Nour. Dr. Nour is a dually trained vascular and interventional neurologist, as well as Medical Director of California's first Mobile Stroke Unit (MSU), bringing extensive expertise in innovative systems of stroke care to the investigator team. UCLA Health site activation is scheduled in two weeks, with first patient enrolment anticipated shortly thereafter.

All five other sites are actively recruiting and ramping up towards reaching the recruitment objective for the Pivotal Trial during first half CY 2026.

About Pivotal (Validation) emu™ Trial

The Pivotal Trial is a prospective, multicentre, blinded investigation across four U.S. and two Australian comprehensive stroke centres, assessing the diagnostic performance of the Company's point-of-care emu™ brain scanner to aid in the assessment of patients with suspected acute stroke. The study's primary endpoint evaluates accuracy against ground truth diagnosis/standard neuroimaging (e.g., CT/MRI), including measures of sensitivity and specificity for haemorrhage detection. Data from the pivotal study are intended to form the basis of the Company's planned De Novo submission to the U.S. Food and Drug Administration.

Following initial training verification, where each site performs a small number of scans, the study has two arms for primary analysis; arm A (N=150 intracranial haemorrhages (ICH)) and arm B (N=150 suspected strokes). Initially, all suspected stroke patients are enrolled into the appropriate study arm. The 'suspected stroke' arm is anticipated to reach 150 participants quickly due to the higher prevalence relative to ICH. The study then progresses to enrolling only confirmed ICH patients. This is readily undertaken as the EMVision emu™ brain scan can be performed directly following the baseline CT where the ICH is originally detected, thus easily identifying suitable candidates for enrolment. The emu™ scanners are housed in or near the radiology bays where the CT is located making for easy deployment. All sites are high volume comprehensive stroke centres. Several of the trial sites each provide care for ≥2,000 stroke and ≥300 ICH patients each year.

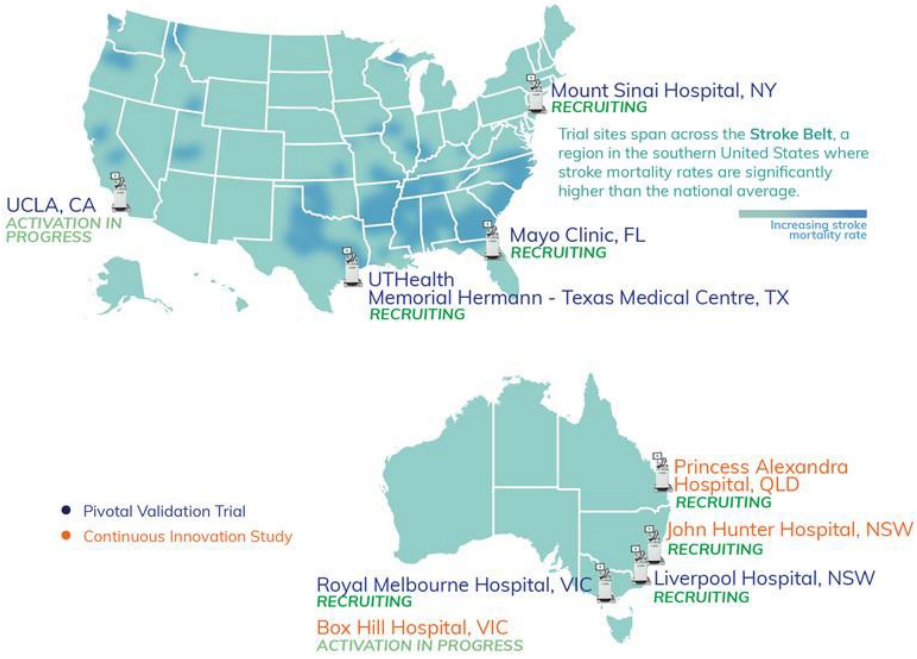
Trial Steering Committee of Key Opinion Leaders assembled

A Trial Steering Committee has been assembled, with the first successful meeting held. The committee will continue to meet throughout the trial to provide independent, advisory oversight and strategic guidance to ensure the Pivotal Trial progresses well in line with its objectives and generates credible, decision-grade evidence for publication, regulatory approval and product adoption. The Trial Steering Committee members include:

- **Co-Chairs Professors Geoffrey Donnan and Stephen Davis**
  - Prof Geoffrey Donnan AO is a professor of Neurology at the University of Melbourne and co-chair, with Prof Stephen Davis AO, of the Melbourne Mobile Stroke Unit program. He is also a past-president of the world Stroke Organisation. He is a former director of the Florey Institute of Neuroscience and with Prof Davis, the co-chair of the Australian Stroke Alliance.
  - Prof Stephen Davis AO, is the co-chair of the Australian Stroke Alliance, a professor of Translational Neuroscience at the University of Melbourne, the Director of the Melbourne Brain Centre at the Royal Melbourne Hospital and a past-president of the World Stroke Organisation.
- **Professor Magdy Selim**
  - Prof Selim is Professor of Neurology at Harvard Medical School. He serves as the Chief of the Division of Stroke and Cerebrovascular Disease and the Director of the Comprehensive Stroke Center at Beth Israel Deaconess Medical Center (BIDMC) in Boston.
- **Associate Professor Christopher Kellner**
  - A/Prof Kellner is a cerebrovascular neurosurgeon at the Mount Sinai Health System in New York City, where he serves as Director of the Intracerebral Hemorrhage Program and Associate Professor of Neurosurgery at the Icahn School of Medicine.
- **Professor Michael Hill**
  - Prof Michael Hill is a Professor for the Departments of Clinical Neurosciences, Community Health Sciences, Medicine and Radiology at the University of Calgary, Canada. He is also Provincial Medical Director for Neurosciences, Stroke, Rehab at Acute Care Alberta.

EMVision CEO and Co-founder, Scott Kirkland, commented "We are incredibly fortunate to be working with many of the institutions that set the standard for stroke care globally and a Trial Steering Committee that is anchored in world-class stroke expertise. We're pleased with our program momentum and look forward to providing further clinical trial updates in due course."

The figure below illustrates the locations of the respective trial sites across the US and Australia



Box Hill Hospital added to Continuous Innovation Study

Recruiting in parallel with the Pivotal (Validation) Trial, the Continuous Innovation Study is progressing well at Princess Alexandra Hospital, Brisbane and John Hunter Hospital in Newcastle.

Box Hill Hospital has been approved for inclusion as the third study site by the central ethics committee and is now in the process of being activated. Box Hill Hospital has received international recognition for achieving World Stroke Organisation Gold status, indicating excellence in stroke care based on key performance indicators. The Continuous Innovation Study aims to support the advancement of additional features and potential future indications for the emu™ device, such as point-of-care traumatic brain injury assessment. This study will be instrumental to the ongoing development and commercialisation of EMVision's technology and devices.

Authorised for release by the Board of the Company.

[ENDS]

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Clinical Investigation Summary

Trial sites are activated in a staggered manner.

Study Title	The EMU Study
Investigational Site	Leading Research Institutions and Comprehensive Stroke Centres in the United States and Australia
Design of the Clinical Investigation	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study of the EMVision emu™ Brain Scanner
Primary Objective	Demonstrate haemorrhage detection sensitivity and specificity >80%
Inclusion Criteria	1. Adults ≥22 years of age 2. Presenting to hospital with acute neurological deficit suspected to be stroke and within 12 hours of symptom onset 3. The use of the EMVision emu™ Brain Scanner will not delay the treatment of the patient 4. CT or MRI brain imaging following clinical evaluation in Emergency Department per standard of care 5. Head size deemed suitable for scanning with the EMVision emu™ Brain Scanner
Exclusion Criteria	• Has received treatment for current (suspected) stroke event prior to initial CT/MRI scan OR EMVision emu™ Brain Scanner scan (such as thrombolysis) • Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography • Contraindications to EMU Brain Scanner scan, such as conditions precluding placement of the scanner, metallic implants in the head, or an inability to lie still during the scan • Pregnant or breastfeeding • Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
Sample Size	300 suspected stroke participants total across 2 study arms: A. Intracranial Haemorrhage – 150 participants B. Other – 150 participants *Note: Training verification on a small number of initial participants is performed at each site prior to enrolment of the above sample*
Duration of Clinical Investigation	Estimated as 6-12 months enrolment period followed by analysis and reporting

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 neurodiagnostic 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.