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ASX Release

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EMU™ PIVOTAL VALIDATION TRIAL COMMENCES

Key Highlights:

- **Pivotal (Validation) Trial to support FDA De Novo clearance of emu™ device commences.**
- **First Australian site – The Royal Melbourne Hospital.**
- **First US site – University of Texas Health Science Center at Houston (UTHealth) Medical School and Memorial Hermann-Texas Medical Center (TMC).**
- **Additional sites to be named and activated shortly.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to advise that it has commenced the Pivotal (Validation) Trial for EMVision's first commercial device, the emu™ bedside brain scanner.

Australian ethics approval has been granted and The Royal Melbourne Hospital has been greenlit to commence as the first Australian hospital after a successful site initiation visit and with operator training in process. The Royal Melbourne Hospital is a world-class comprehensive stroke centre, and home to the Melbourne Brain Centre – the largest brain research collaboration in the southern hemisphere. EMVision is proud to continue its close collaboration with the team at The Royal Melbourne Hospital, who were instrumental to the success of the prior pre-validation EMView study.

In addition, an emu™ device has been shipped to the first US site, University of Texas Health Science Center at Houston (UTHealth) Medical School and Memorial Hermann-Texas Medical Center (TMC). UTHealth Houston has a long tradition of stroke care innovation, having pioneered the use of tissue-type plasminogen activator (tPA), a life saving treatment for acute ischaemic stroke, and mobile stroke units to expedite its delivery. A site initiation visit is planned for the coming weeks.

Additional Pivotal (Validation) Trial sites in the US and Australia will be named and activated shortly.

About the EMVision emu™ Brain Scanner

The EMVision emu™ Brain Scanner is a non-invasive, non-ionising device that uses ultra-high frequency radiofrequency (RF) scanning technology, combined with advanced AI-based algorithms, to assist in point-of-care stroke diagnosis. Prior to the Pivotal (Validation) Trial, EMVision's emu™ Brain Scanner has been the subject of a series of successful clinical studies, ranging from healthy human volunteer studies, through to a proof-of-concept study and a large multi-centre study ('EMView') of participants experiencing acute suspected stroke.

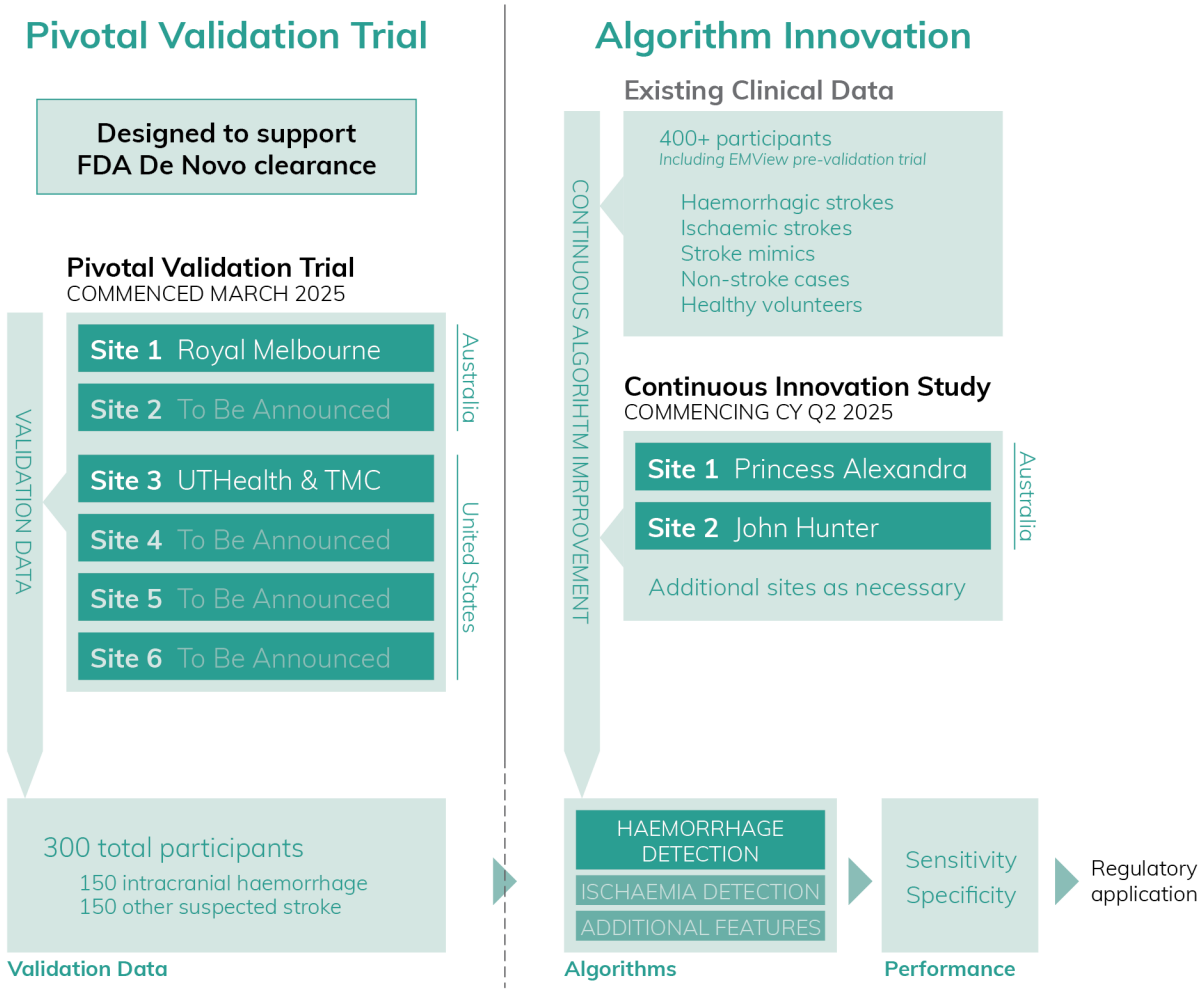
About the Pivotal Clinical Trial

The emu™ Pivotal (Validation) Trial has an estimated enrolment period of 6-12 months, followed by analysis and reporting of the data. The primary objective is the demonstration of haemorrhage detection sensitivity and specificity of >80%. Determining the presence of haemorrhage is critical to selecting the treatment pathway, with the alternative ischaemic stroke diagnosis requiring a divergent treatment approach. Three hundred (300) suspected stroke participants will be enrolled across 4 sites in the US and 2 sites in Australia. Data will be collected from these participants in a way that allows sequential validation of additional features, such as ischaemia detection, without undertaking an additional full validation trial. To ensure scientific

validity, EMVision is blinded to certain study data (i.e. results will be analysed at the conclusion of enrolment). The Company intends to report on recruitment rates during the trial. The clinical research organisation (CRO) is Vastrax, a leading full-service CRO specialising in clinical neurovascular studies. Vastrax brings a wealth of expertise and experience in this field, including their involvement in prior studies of innovative stroke diagnostics. The Pivotal (Validation) Trial will have an independent Trial Steering Committee (TSC) and Data Safety Monitoring Board (DSMB), who will meet periodically to ensure the study progresses effectively and safely, as is best practice. The trial is designed to support FDA De Novo clearance for EMVision's first commercial product, the emu™ point-of-care Brain Scanner. In addition, the emu™ device is anticipated to become the predicate device for EMVision's second commercial product, the First Responder device, allowing an expedited 510(k) FDA pathway for the pre-hospital market.

Continuous Innovation Strategy

In parallel, as previously advised, EMVision will conduct a 'Continuous Innovation Study' where additional patients will be scanned at multiple sites in Australia outside of the Pivotal Trial, including the Princess Alexandra Hospital, Brisbane and John Hunter Hospital. The Continuous Innovation Study data will be used to progress the development of additional device features and expand the training library for EMVision's diagnostic AI algorithms. EMVision observed meaningful performance increases in the sensitivity/specificity of its diagnostic AI algorithms during the 'EMView' study when additional training data was utilised. This study is separate to, and isolated from, the Pivotal (Validation) Trial dataset.



Neurologist and Co-chair of the Australian Stroke Alliance, Professor Stephen Davis AO said "The Australian Stroke Alliance is pleased to see trials of the emu™ point-of-care brain scanner in a hospital setting. We are eager to see the diagnostic power of the emu™ as its performance will also help inform the likely success of the First Responder device – a portable brain imaging tool that the Stroke Alliance aims to take on the road and in the air with emergency paramedics attending code strokes. This trial will support our quest to provide urgent onsite brain imaging - a critical first step in the stroke treatment pathway."

EMVision CEO, Scott Kirkland, commented "We are delighted to announce the commencement of the Pivotal (Validation) Trial for the emu™ point-of-care Brain Scanner to support market entry. This important milestone marks the culmination of many years of hard work and dedication from our team and our clinical collaborators, in pursuit of the development and validation of world-first neurodiagnostic technology that has the potential to significantly reduce the global burden of stroke. We look forward to activating our additional sites in the near term and reporting on our trial progress."

Authorised for release by the Board of the Company.

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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.