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ASX Release

KEY DEVELOPMENTS IN PIVOTAL TRIAL AND CONTINUOUS INNOVATION STUDY

Key Highlights:

- **Five of the six Pivotal (Validation) Trial sites now actively enrolling and scanning patients.**
- **Luminary sixth Pivotal (Validation) Trial site preparation in progress.**
- **Approval also received to commence Continuous Innovation Study for stroke and traumatic brain injury patients at two leading hospitals in Australia.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide a progress update in relation to the Pivotal (Validation) Trial and Continuous Innovation Study for EMVision's first commercial device, the emu™ bedside brain scanner.

Pivotal (Validation) Trial

Five of the six Pivotal (Validation) Trial sites are now actively enrolling and scanning patients. The site initiation visit and device training at the third US site, Mount Sinai (New York) has been successful, with recruitment underway. The final sixth site for our Pivotal (Validation) Trial is expected to be announced shortly, having recently cleared their local Institutional Review Board.

As previously advised, the Pivotal (Validation) Trial for our emu™ device has an estimated enrolment period of 6-12 months, followed by analysis and reporting of the clinical data. Up to 300 suspected stroke patients will be enrolled across 4 sites in the US and 2 sites in Australia. All trial sites are luminary, high volume comprehensive stroke centres.

The trial is designed to support FDA De Novo clearance for EMVision's first commercial product, the emu™ point-of-care bedside brain scanner. De Novo clearance opens global market access opportunities, allowing the emu™ brain scanner to improve neurodiagnostic access through its ease of use, non-ionising radiation and portability.

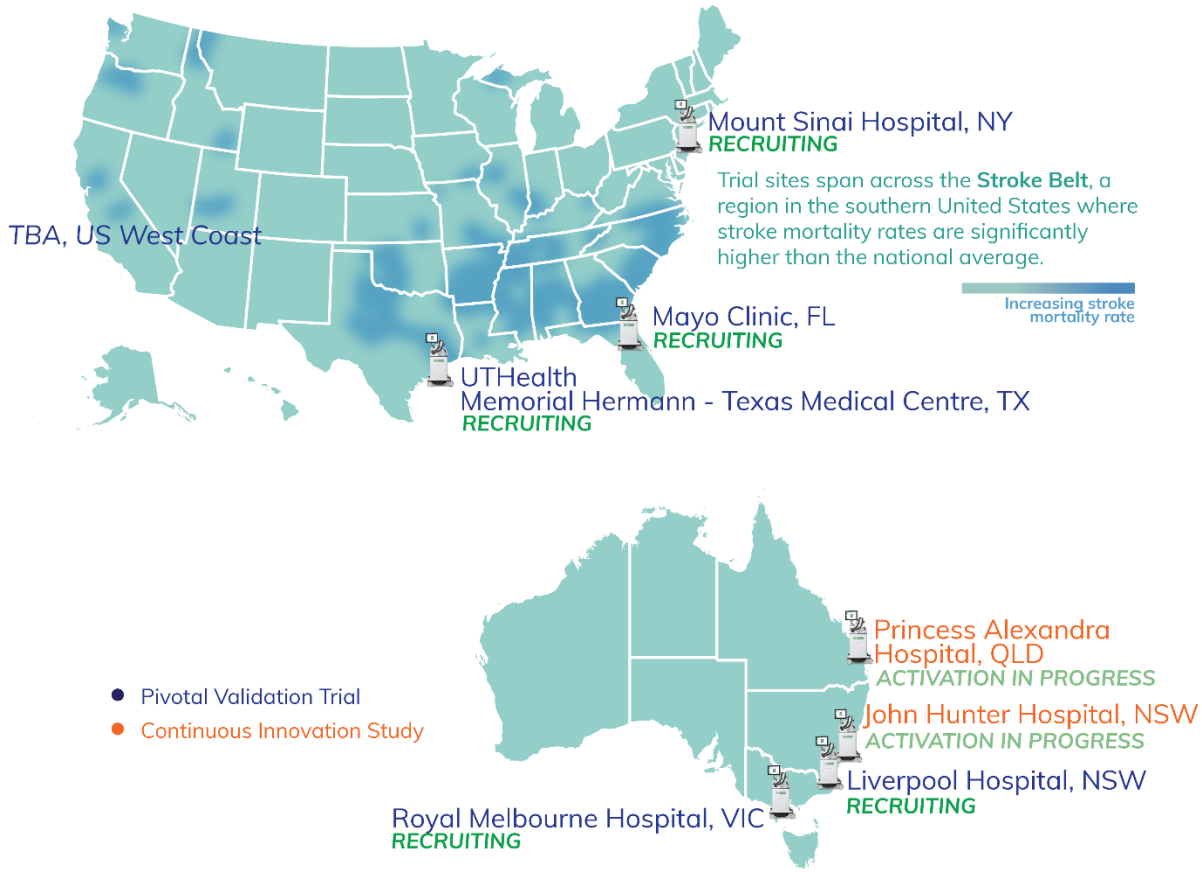
The emu™ device is then anticipated to become the predicate device for EMVision's second commercial product, the First Responder device, allowing an expedited 510(k) FDA pathway for the pre-hospital market (i.e. ambulance and aeromedical services).

Continuous Innovation Study

In parallel to the Pivotal (Validation) Trial for the emu™ device, EMVision is implementing a cost-effective strategy for continued device innovation, algorithm enhancement and data to support indication expansion (traumatic brain injury). This initiative is referred to as EMVision's Continuous Innovation Study. Ethics approval has been received to commence scanning patients with suspected stroke or traumatic brain injury at Princess Alexanda Hospital (Brisbane) and John Hunter Hospital (Newcastle). Both sites are high volume Comprehensive Stroke and Level 1 Trauma Centres. A device has been shipped to Princess Alexandra, with site initiation and device training underway this week and recruitment to commence this month. John Hunter

Hospital is also anticipated to be activated later this month. This study will be instrumental to the ongoing development and commercialisation of EMVision's technology and devices.

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



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.