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ASX Release

FIRST RESPONDER AEROMEDICAL STUDY COMMENCES

Key Highlights:

- **Live operational evaluation of EMVision's portable First Responder device with Royal Flying Doctor Service (RFDS) teams in aeromedical and remote environments.**
- **Study assesses usability, workflow integration, training requirements, scan success rates, and environmental robustness.**
- **Findings will de-risk operational deployment, inform final commercial device design and support regulatory and commercial pathways for the First Responder device.**
- **RFDS collaboration provides access to diverse, real-world pre-hospital scenarios spanning long distances, limited infrastructure, and time-critical care settings.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to advise that it has commenced an aeromedical feasibility and usability study of its First Responder device in collaboration with the Royal Flying Doctor Service (RFDS), Australian Stroke Alliance (ASA) and South Australian Ambulance Service (SAAS).

Study objectives

The study will enrol aeromedical retrieval patients and will collect operator feedback and EMVision brain scans including workflow metrics generated from scan procedures. The evaluation focuses on operational feasibility and usability, including integration into aeromedical workflows, in the pre-hospital setting. The study hypothesises that the proposed EMVision First Responder Brain Scanner aeromedical workflow is suitable for use in an emergency aeromedical stroke response. Data will be used to refine commercial product design, training materials and support subsequent clinical and regulatory activities. The study is expected to complete during CY Q1 2026.

Study significance

Early, accurate diagnosis of acute stroke in pre-hospital and remote settings remains a major unmet need. Aeromedical retrievals are challenged by vast distances and inaccessibility of neuroimaging infrastructure in rural and remote areas, thereby preventing timely diagnosis and treatment. Aeromedical retrievals routinely span thousands of kilometres with median stroke transfer times of ~238 minutes. The transfer duration takes patients outside time windows for most stroke treatments, highlighting the tyranny of distance's contribution to poorer patient outcomes in rural and remote areas. Time is critical for both ischemic and hemorrhagic strokes, as faster treatment preserves more brain tissue, improving outcomes and survival.

EMVision seeks to improve care accessibility and equality in patient outcomes in these settings, through the deployment of a cost-effective, portable and easy-to-use brain scanning device. The First Responder device is designed to empower healthcare teams to make earlier, evidence-based decisions for stroke patients, supporting faster triage, transfer or treatment where it's needed most.

EMV CEO and Co-Founder Scott Kirkland commented: “Commencing this feasibility and usability program with the Royal Flying Doctor Service is a pivotal step in de-risking real world deployment of our First Responder device. As RFDS teams operate in some of the toughest environments on earth, their feedback and the study data will be invaluable to progressing our device towards commercial readiness and regulatory submissions”.

Dr Zoe Schofield, Head of Strategic Research Projects and Principal Investigator, EMVision First Responder Aeromedical Study, Royal Flying Doctor Service (RFDS), commented: “The RFDS is committed to advancing innovations that improve access to timely, high-quality care for patients in rural and remote Australia. We are thrilled to collaborate with EMVision on this important project.”

Australian Stroke Alliance Co-chair, Professor Geoffrey Donnan AO commented: “We welcome this important step towards urgent, in-field brain scanning. It’s a world-first trial of ingenious Australian Medtech and meets our fundamental aim to improve stroke care for rural and remote patients. The faster a stroke is diagnosed, the sooner we can treat and prevent disability.”

EMVision’s First Responder device pictured with RFDS team member

Next steps

- Ongoing capture of usability and operational data over the coming months.
- Iterative device and workflow refinements based on study findings.
- Preparation for subsequent data collection, validation and regulatory activities to support First Responder market entry and commercialisation.

Authorised for release by the Board of the Company.

[ENDS]

Clinical Investigation Summary (Aeromedical)

Study Title	Usability and Workflow Implementation of the EMVision First Responder Brain Scanner in Aeromedical Retrievals.
Investigational Site	Royal Flying Doctor Service, Adelaide Base.
Design of the Clinical Investigation	Single-arm, non-randomised, workflow implementation of the EMVision First Responder device.
Objectives	To determine the workflow impacts and usability of in-field (i.e., not at a hospital) brain scan procedures conducted during aeromedical retrievals.
Endpoints	• Usability of the device as assessed by users • Workflow metrics • Safety
Inclusion Criteria	1. Adults ≥ 18 years of age 2. Patients receiving an aeromedical transport 3. Head size deemed suitable to fit the device 4. The use of the EMVision First Responder Brain Scanner will not delay the treatment of the patient
Exclusion Criteria	1. Patients who cannot freely provide consent. 2. Contraindicated to the EMVision First Responder scan. 3. Patients suffering from or suspected of suffering from an acute head injury (e.g., concussion, scalp laceration, skull fracture). 4. Patients suffering from or suspected of suffering from an acute neurological condition (e.g., stroke, seizure, migraine). 5. Unable to lie still for the duration of the scan. 6. Any other medical or logistical contraindication at the discretion of the aeromedical retrieval team or attending physician. ***Note:*** *Exclusion criteria 3 and 4 are due to potential for confusion of the patient resulting from a brain scan unrelated to their condition.*
Sample Size	The research team will actively recruit participants for a total period of 8 weeks. It is anticipated that during this time approximately 30 participants will be enrolled.
Duration of Clinical Investigation	The total study duration including site training, site activation, closure is anticipated to be <6 months.

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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.