4/10/22

ASX Release

EMvision Medical Devices Ltd
ACN 620 388 230
Level 10, 12 Creek Street,
Brisbane Qld 4000
02 8667 5337
contact@emvision.com.au

ETHICS APPROVAL RECEIVED FOR MULTI-CENTRE CLINICAL TRIAL

Highlights:

- *Human Research Ethics Committee (HREC) approval received for multi-centre clinical trial.*
- *Study to take place at leading comprehensive stroke centres including Liverpool Hospital, Royal Melbourne and the Princess Alexandra Hospital, Brisbane.*
- *Pre-validation phase of the study aims to verify hardware and safety and to provide acute stroke/stroke mimic data for AI algorithms. The subsequent validation phase will confirm efficacy. Completion of both stages is expected to generate the prerequisite data for EMVision's first regulatory approvals.*
- *Study expected to show that EMVision's portable brain scanner can provide crucial insights to enable clinicians to make critical decisions earlier, when time matters, at the point-of-care.*
- *Further $1.2 million in non-dilutive milestone payments triggered under the Australian Medical Research Future Fund (MRFF) grant program in partnership with the Australian Stroke Alliance.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company"), a medical device company focused on the development and commercialisation of medical imaging technology, is pleased to announce the receipt of Human Research Ethics Committee (HREC) approval for its multi-centre clinical study which will take place at Liverpool Hospital, Royal Melbourne and the Princess Alexandra Hospital, Brisbane.

Ethics approval is confirmation that EMVision has completed the necessary safety testing required to commence its multi-centre clinical trial in Australia. Activation of the first site, Liverpool Hospital, under the direction of principal investigator, Dr Dennis Cortado, will proceed in the near-term following delivery of commissioned units and governance "green light" letter receipt.

The clinical study follows EMVision's prior successful pilot study with 50 patients, which demonstrated encouraging capability to accurately classify and localise stroke types. The upcoming clinical trial consists of two phases. The primary aim of the initial pre-validation phase is to verify hardware and safety and to provide acute stroke/stroke mimic data for AI algorithms. The subsequent validation phase aims to confirm sensitivity and specificity (efficacy). Completion of both stages is expected to generate the prerequisite data for EMVision's first regulatory approvals. The "Clinical Investigations Roadmap" diagram below provides a summary of the clinical trial.

In addition, a further $1.2 million in milestone grant payments have been activated pursuant to the partnership with the Australian Stroke Alliance (ASA) to develop mobile diagnostic imaging for road and air ambulances, "Algorithm validation studies – Planning commenced and in progress" and "Ethics clearance received for algorithm validation / multi-site clinical study". The Company has submitted invoices and supporting documentation as required in relation to these milestones to the ASA for review and payment. Further details

on the key terms and milestones of this grant are outlined in an ASX announcement released on 16 September 2021 titled “Australian Stroke Alliance and EMVision Sign $8m Project Agreement”.

EMVision CEO, Dr Ron Weinberger commented: “This is a significant milestone for EMVision on the journey to commercialise our first-generation product. Knowing that our device has gone through rigorous assessment and has been given a tick of approval to enter the clinical environment is a meaningful development. This trial will provide us with significant information to learn about the range of capabilities of our technology to inform clinical decision making in stroke care.”

Clinical Investigations Roadmap

The sites will be activated progressively, commencing with Liverpool Hospital. All sites selected are major stroke centres that treat significant volumes of stroke patients each year. The Clinical Research Organisation (CRO) is Avania Medical.

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:** To be advised as required **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

Authorised for release by the Board of the Company.

[ENDS]

For further information, media or investor enquiries, please contact:

Andrew Keys	Sling & Stone	Scott Kirkland
Investor Relations	Media and Communications	Executive Director
+61 400 400 380	emvision@slingstone.com	+61 2 8667 5337
Andrew.keys@keysthomas.com	02 8073 5390	skirkland@emvision.com.au

About EMVision Medical Devices

EMVision Medical Devices Limited is focused on the development and commercialisation of medical imaging technology. The Company is developing and seeking to commercialise a potentially cost effective, portable, medical imaging device using electromagnetic microwave imaging for diagnosis and monitoring of stroke and other medical applications. The technology is the result of over 10 years of development by researchers at the University of Queensland. The team of approximately 20 researchers is led by co-inventor Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging. EMVision's Chief Scientific Officer is Professor Stuart Crozier, who is a co-inventor and is globally renowned for creating technology central to most MRI machines manufactured since 1997. EMVision's CEO, Dr Ron Weinberger, is the Former Executive Director and CEO of Nanosonics' (ASX:NAN), a $1.2 billion market cap healthcare company. Dr Weinberger has over 25-years' experience developing and commercialising medical devices. During his time at Nanosonics, Dr Weinberger co-developed the company's platform technology and launched their breakthrough product 'Trophon' globally, which would go on to become the gold standard for infection prevention. Dr Weinberger was instrumental in transforming Nanosonics from a research and development company to one of Australia's leading medical device commercialisation success stories.

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.