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ASX Release

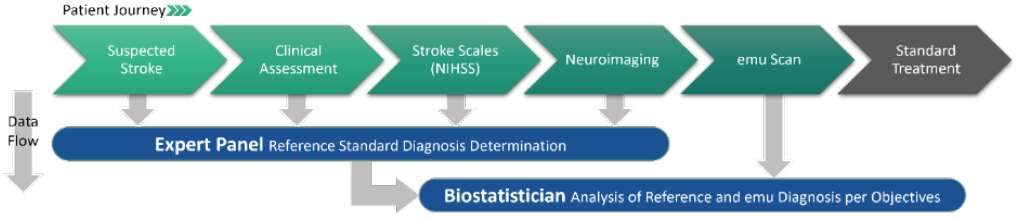
EMV PREPARES FOR VALIDATION TRIAL FOLLOWING POSITIVE FDA ENGAGEMENT

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to advise that it has received valuable insights and guidance from the FDA on its planned validation trial to support the emu™ De Novo regulatory clearance pathway.

A consultative meeting with the FDA was held as part of EMVision's planned validation trial preparation via the FDA's Q-submission program, a mechanism whereby industry may gain alignment with FDA prior to final regulatory submission. The meeting answered a number of critical questions relating to our validation program, including key parameters of the validation study, sites outside the US and statistical powering. A synopsis of the validation trial is provided below.

The meeting reinforced our confidence that EMVision's strategic direction is appropriately aligned with FDA requirements. EMVision will continue to engage with the FDA to ensure alignment up to regulatory submission. We are preparing ethics as well as contracts and other administrative elements with activation anticipated in the coming months. EMVision's leadership is visiting US investigational sites for advanced site engagement, including preliminary device training, prior to participating at the Society of Vascular and Interventional Neurology (SVIN) annual meeting in November. Announcement of sites to follow in due course. In parallel, human factors engineering studies are in process to extend usability to the range of potential intended users and use environments.

Study Design:	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study
Investigational Sites:	Minimum 5 stroke centres including minimum 3 based in USA
Number of Participants:	Up to 300 patients (indicative)
Inclusion Criteria:	Adults with untreated acute suspected stroke
Exclusion Criteria:	Unable to receive CT/MRI (i.e. contrast allergy) or EMV scan (i.e. inadequate time)
Primary Objectives:	Demonstrate sensitivity and specificity of neurodiagnostic algorithms exceed FDA targets[1]
Secondary Objectives:	Confirm safety, usability, reliability and limit-of-detection



[1] Relevant previously accepted minimum performance targets by the FDA for devices in the area of large vessel occlusion stroke and intracerebral haemorrhage: 80% sensitivity and specificity. See decision summary for De Novo DEN170073 for ContaCT (Viz.AI) and 510(k) summary for 510(k) K193658 for Viz ICH (Viz.AI).

Indicative study design and may be modified. Further detail on the validation trial design will be provided on receipt of ethics approval, prior to its commencement.

Authorised for release by the Board of the Company.

[ENDS]

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

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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 neuroimaging 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.