ASX ANNOUNCEMENT

28 April 2025

Institutional Review Board approval for innovative mental health trial with US Department of Veterans Affairs

Highlights:

- **IRB approval received for trial protocol, allowing for commencement of clinical trial to screen for a current major depressive episode (cMDE) using TRI's technology**
- **Trial to be undertaken alongside the Greater Los Angeles Veterans Research and Education Foundation (GLAVREF) and the United States Department of Veterans Affairs ('VA')**
- **The VA is a branch of the US federal government and provides lifelong healthcare to eligible veterans via 170 medical centres and outpatient clinics across the US**
- **The VA's Veterans Health Administration is America's largest integrated health care system – via 1,380 healthcare facilities it serves 9.1m veterans per annum**
- **GLAVREF is a US not-for-profit organisation that supports VA approved research**
- **Cooperative Research and Development Agreement ('CRADA') executed with GLAVREF and the VA following IRB approval to formalise collaboration**
- **Trial to utilise TRI's single-channel mental health screening algorithm which uses heart rate and heart rate variability to accurately conduct sleep staging and screen for cMDE**
- **Trial to recruit 60 patients across multiple sites with study completion expected within 12 weeks from commencement – First patient enrolments expected in the very near term**
- **Results have potential to unlock major commercialisation opportunities for expanded use of TRI's technology**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to advise it has received Institutional Review Board (IRB) approval for its proposed clinical trial protocol, being undertaken alongside the Greater Los Angeles Veterans Research and Education Foundation (GLAVREF) and the United States Department of Veterans Affairs ('VA') (refer ASX announcement: 13 March 2025). As part of the development, TrivarX has also entered into a Cooperative Research and Development Agreement ('CRADA') with GLAVREF and the VA to formalise the relationship.

IRB approval allows for commencement of the trial. First patients anticipated to be enrolled in the coming weeks.

The trial alongside the VA, will assess the sleep scoring accuracy of TrivarX's single-channel ECG algorithm comparing it to gold standard human-rated polysomnography, and will evaluate the algorithm's current Major Depressive Episode (cMDE) determination against the clinical gold standard of using the Mini International Neuropsychometric Interview (MINI) administrated by a health professional. In addition to using the single-lead ECG signal, patients will also wear a wrist-worn wearable device during the night providing the company with additional data for further R&D and commercialisation.

A total of 60 trial participants with suspected sleep apnea will be sourced from multiple sites including the VA's network in the US. The trial is expected to take approximately 12 weeks from commencement.

TrivarX's single-channel algorithm is an extension of lead asset, MEB-001. The algorithm accurately conducts sleep staging and screens for cMDE in subjects using heart rate (HR) and heart rate variability (HRV) metrics alone. Results from the Company's Phase 2 trial on 195 patients demonstrated a sensitivity of 87% (95% CI 74-95%) and specificity of 67% (95% CI 62-73%).

The US Department of Veterans Affairs is a cabinet level executive branch department of the federal government charged with providing lifelong healthcare services to eligible military veterans via 170 VA medical centres and outpatient clinics located throughout the US.

Commentary:

Non-executive Chairman, David Trimboli said: *"We are very pleased to have received IRB approval, as well as formalised this collaboration with the US Department of Veterans Affairs following the execution of a separate CRADA. The approval follows a considerable amount of planning and liaison with both the VA and GLAVREF, to ensure that the clinical trial protocol is of the highest possible standard.*

"The Company is now focused on finalising site selection and patient recruitment initiatives. Given the work undertaken to date, we expect first enrolments in the coming weeks with results to follow 12-weeks after. Additional updates in this regard will be made as developments materialise."

This announcement is authorised for release by the Board of Directors of TrivarX Limited.

ENDS

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About TrivarX Limited:

TrivarX (ASX: TRI) (OTCPINK: MDBIF) is a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. The Company was founded in Australia, with offices located in Perth (WA) and Minneapolis (MN, USA). TrivarX is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au