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TrivarX and US Department of Veterans Affairs to launch innovative mental health clinical trial

Highlights:

- TrivarX, alongside the Greater Los Angeles Research and Education Foundation (GLAVREF) and the US Department of Veterans Affairs (VA) to perform a clinical trial to screen for a current major depressive episode (cMDE) using TRI's technology
- GLAVREF is a US-based not-for-profit organisation that supports VA approved research, and 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
- TrivarX has worked with GLAVREF and the VA to submit a trial protocol to the VA's Institutional Review Board and expects the protocol to be approved in the upcoming weeks
- Trial to utilise TRI's ground-breaking single-channel mental health screening algorithm which uses only heart rate (HR) and heart rate variability (HRV) to accurately conduct sleep staging and screen for cMDE
- Previous algorithm validation testing showed sensitivity of 87% (95% CI 74-95%) and specificity of 67% (95% CI 62-73%)
- Trial to recruit 60 patients across multiple sites with study completion expected within 12 weeks from commencement
- Initiative has the potential to unlock significant commercialisation opportunities for the expanded use of TRI's technology
- Study will be led by Principal Investigator, Dr Jennifer Martin, a nationally recognised expert in insomnia disorder and mental health

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the Company') (ASX: TRI) is pleased to announce that it will conduct a clinical trial using the Company's ground-breaking, single-channel ECG mental health screening algorithm (refer ASX announcement: 7 November 2024). The Company has worked alongside the Greater Los Angeles Veterans Research and Education Foundation (GLAVREF) and the United States Department of Veterans Affairs ('VA') to submit a trial protocol to the VA's Institutional Review Board ('IRB') which is pending approval. The Company has also negotiated a Cooperative Research and Development Agreement ('CRADA') with GLAVREF and the VA, which is expected to be signed on receipt of IRB approval.

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.

TrivarX's single-channel algorithm is an extension of the Company's 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%).

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This trial with the VA will assess the sleep scoring accuracy of the single-channel ECG algorithm comparing it to gold standard human-rated polysomnography, and will evaluate the algorithm's cMDE determination against the clinical gold standard of using the Mini International Neuropsychometric Interview (MINI) administered by a health professional. 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.

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.

Dr Jennifer Martin PhD, a nationally recognised expert in insomnia disorder will be appointed as Principal Investigator. She is a recent past president of the American Academy of Sleep Medicine (AASM) and the AASM Foundation.

Dr Martin is board-certified in behavioural sleep medicine by the American Board of Sleep Medicine (ABSM) and holds multiple prominent roles, including Associate Director for Clinical and Health Services Research at the VA Greater Los Angeles Healthcare System's Geriatric Research, Education, and Clinical Center. She is also a professor of medicine at the David Geffen School of Medicine at UCLA.

This partnership with GLAVREF and the US Department of Veterans Affairs marks a significant milestone in the development of TrivarX's next-generation algorithms, which focus on at-home monitoring of sleep and mental health.

Commentary:

Principal Investigator, Dr Jennifer Martin said: *"Depression is a widespread and debilitating condition, which is common amongst military veterans. We look forward to commencing this study with TrivarX to explore the potential of its technology for depression screening."*

Non-executive Chairman, David Trimboli said: *"This trial marks another important step forward in our broader clinical development strategy and follows strong preliminary results for the Company's single-lead algorithm in initial patient data testing."*

"In that context, we are pleased to confirm this partnership with an organisation of the calibre of the US Department of Veterans Affairs. As a federal government department focused on the health and welfare of US military veterans, the VA has a direct interest in achieving improved health outcomes for its members with the help of cutting-edge technology."

"This trial is in alignment with those objectives, and also has the potential to open up an expanded addressable market for TrivarX's suite of novel algorithms targeting an improvement to the standard of care by objectively screening for mental health conditions."

"Working at trial sites with an industry leader in Dr Jennifer Martin as lead investigator, we look forward to initiating patient recruitment and advancing the clinical pathway for what is an exciting new application of the Company's technology."

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

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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.otcm Markets.com and www.asx.com.au

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