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Positive results from US-veteran mental health trial highlight clinically meaningful, objective detection of depression symptoms

Highlights:

- Results taken from clinical trial to screen for a current major depressive episode (cMDE) in veterans using TRI's single-lead technology
- Trial undertaken with the Greater Los Angeles Research and Education Foundation (GLAVREF) and US Veterans Affairs (VA) Greater Los Angeles Healthcare System
- Results from 57 of 60 total patients included:
 - Single-lead algorithm sensitivity: 97% (95% CI 84-100%)
 - Single-lead algorithm specificity: 64% (95% CI 46-82%)
 - MEB-001 sensitivity: 88% (95% CI 71-96%)
 - MEB-001 specificity: 68% (95% CI 47-85%)
- Data from the study also highlight that sleep disturbance, cMDE and post traumatic stress disorder (PTSD) are highly prevalent in veterans
- Clinical trial has shown that TRI's single-lead algorithm can support early detection of cMDE, which aligns with the VA's priorities and strengthens the Company's commercial position

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the Company') (ASX: TRI) is pleased to provide positive results from the Company's clinical trial alongside the Greater Los Angeles Research and Education Foundation (GLAVREF) and Veterans Affairs (VA) Greater Los Angeles Healthcare System evaluating its novel single-lead ECG algorithm to screen for current major depressive episodes (cMDE) in veterans with suspected sleep apnoea (refer ASX Announcement 28 April 2025).

The trial utilised the Company's single-channel ECG algorithm, which is an extension of lead asset, MEB-001. The algorithm accurately performs sleep staging and detects cMDE in subjects using only heart rate (HR) and heart rate variability (HRV) metrics.

Results highlight the potential for TRI's single-channel algorithm to deliver a differentiated, objective screening platform for mental health conditions.

Clinically meaningful results highlight algorithm potential in veterans:

The trial's objective was to assess the sleep scoring accuracy of TrivarX's single-channel ECG algorithm, comparing it to gold standard human-rated polysomnography (PSG), and evaluate the algorithm's cMDE determination against the clinical gold standard of using the Mini International Neuropsychiatric Interview (MINI) administrated by a health professional.

Analysis was taken from 57 of 60 participants, enrolled through the VA Greater Los Angeles Healthcare System. Three participants were not included in analysis due to insufficient data capture. Amongst participants, 48 participants or 80% were male, while the remaining 12 patients or 20% were female.

Of the subject sample, the prevalence of cMDE was 58.3%. A descriptive analysis of the sample demonstrated that cMDE coexisted with Post Traumatic Stress Disorder (PTSD) in 72% of patients, as well anxiety disorders, across 77% of participants.

Both the Company's MEB-001 and single-channel algorithms demonstrated strong sensitivity for cMDE compared to clinician diagnosis of 97% and 88% respectively, with specificities of 64% and 68%.

Analysis of the final results highlighted similar performance between MEB-001 and the single-lead algorithm, underpinning additional validation for the Company's innovative single-lead offering. Results are also consistent with previous testing across 295 independent data subsets from the Company's phase 2 trial (refer ASX announcement: 7 November 2024).

A summary of the Phase 2 trial analysis and recently completed VA trial is as follows:

Measure:	Single-lead (Phase 2 data) N=295	MEB-001 (Phase 2 data) N=295	Single lead (VA trial) N=57	MEB-001 (VA trial) N=57
Sensitivity	87% (95% CI 74-95%)	87% (95% CI 73-95%)	97% (95% CI 84-100%)	88% (95% CI 71-96%)
Specificity	67% (95% CI 62-73%)	72% (95% CI 66-77%)	64% (95% CI 46-82%)	68% (95% CI 47-85%)

Strategic implications and commercial outlook:

The results generated from TrivarX's single-lead algorithm demonstrate the potential to deliver a differentiated, objective screening platform for mental health conditions. By extracting clinically relevant signals from a single ECG lead, the technology offers a scalable and data-driven approach to mental health assessment, addressing a recognised need for objective tools to complement traditional, subjective expert-administered screening methods.

Importantly, the algorithm is designed to integrate seamlessly into existing clinical workflows, including established sleep disorders clinic environments, without introducing additional operational burden. This compatibility supports efficient adoption within large healthcare systems and enables deployment at scale using existing infrastructure.

These capabilities support earlier identification of at-risk individuals, facilitate more personalised intervention strategies, and enable population-level monitoring and health initiatives. Collectively, the outcomes align closely with VA and U.S. Department of Defense priorities around veteran mental health, while strengthening TrivarX's commercial positioning and regulatory pathway for broader clinical adoption.

Management commentary:

Principal Investigator, Dr Jennifer Martin said: *"This novel approach capitalizes on information that is collected as part of routine tests for sleep disorders and adds to our ability to detect mental health symptoms in patients who might not otherwise undergo mental health screening. The results of this trial are promising in terms of helping us to identify individuals in need of mental health treatments in the future."*

Non-executive Chairman, David Trimboli said: *"These results represent a significant clinical validation milestone for TrivarX and provide compelling evidence of the real-world performance of our single-lead ECG algorithm in a high-need veteran population. Achieving sensitivity of 97% for the detection of current major depressive episodes demonstrates the algorithm's ability to objectively identify individuals who may otherwise remain undiagnosed using traditional screening approaches. Importantly, the performance of the single-lead algorithm is consistent with, and in some cases exceeds, that of our established MEB-001 asset, while requiring only a single ECG channel."*

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The trial also highlights the high prevalence and co-existence of sleep disturbance, depression and PTSD in veterans, reinforcing the need for scalable, objective screening tools that can be embedded into existing care pathways.

The ability to deploy this technology seamlessly within VA sleep clinics, without adding operational burden, aligns strongly with the VA's focus on early identification, improved access to care and population-level mental health initiatives. We believe these results materially strengthen TrivarX's commercial and regulatory positioning and support ongoing discussions around broader clinical adoption within large healthcare systems."

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.otcmarkets.com and www.asx.com.au