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ASX ANNOUNCEMENT

10 July 2024

Phase 2 Sleep Signal Analysis for Major Depressive Episode (SAMDE) study completed with results expected imminently

Highlights:

- **400 patient milestone met in TRI's Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study utilising MEB-001 highlighting completion of trial**
- **MEB-001 is TrivarX's proprietary algorithm which utilises artificial intelligence (AI) to assist with the effective screening of a current Major Depressive Episode (cMDE)**
- **Data now being reviewed by TRI personnel with MEB-001 performance results expected imminently**
- **Results of phase 2 SAMDE study to inform ongoing engagement with United States (US) Food and Drug Administration (FDA) approval for MEB-001**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to advise that it has completed its Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study utilising its proprietary AI-backed algorithm, MEB-001.

The study aims to continue to validate its innovative algorithm (MEB-001) to assist in the screening and diagnosis of a current Major Depressive Episode (cMDE) in test subjects. The Company is now assessing all available data generated from the 400 patients enrolled and will provide preliminary results imminently.

TrivarX's Phase 2 SAMDE study was undertaken across 15 sleep centres in the US. During the trial, clinicians (CRO) administered a Mini International Neuropsychiatric Interview (MINI) for each subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding current Major Depressive Episode status.

The trial follows pleasing Phase 1 results, which indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value (PPV) of 35.38%, and a Negative Predictive Value (NPV) of 92.11% when tested within the development sample with a cross-validation protocol (refer ASX announcement: 24 July 2023).

The Phase 2 SAMDE study results study will provide further regulatory validation for its proprietary algorithm prior to further engagement with the US Food and Drug Administration (FDA), which is scheduled for the coming months.

Management commentary:

Non-executive Chairman, David Trimboli said: *"We are very pleased to have completed our comprehensive Phase 2 SAMDE study and I would like to take this opportunity to thank our clinical field team and research partners for their continued work and support.*

"The Company's in-house personnel are now rapidly undertaking data analysis on patient reports generated, which will be used to provide updated MEB-001 performance results. Following our Phase 1 initiative and ongoing algorithm training, the Company is confident of positive results for MEB-001 – a clinically-backed AI solution that aims to provide more effective screening of a current Major Depressive Episode (cMDE) and achieve improved patient health outcomes. These results will help inform our ongoing dialogue with the US FDA and commercial pathway and we look forward to reporting them shortly."

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. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. 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

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