**ASX ANNOUNCEMENT**

**20 November 2023**

# 15 sleep centres on-boarded to fast track Phase 2 Sleep Signal Analysis of Depression Burden (SAMDE) study

**Highlights:**

- **On-boarding completed across 15 sleep centres in the US – exceeding initial target of 14 sites for Phase 2 Sleep Signal Analysis for Current Major Depressive Episode study**
- **Additional centre added following high level of in-bound enquiries from industry participants**
- **Three sites added across Texas through Comprehensive Sleep Medicine Associates ("CSMA") – expected to accelerate patient enrolment over coming weeks**
- **CSMA is a leading Texas-based organisation with a mission to provide comprehensive, high quality care to patients with sleep disorders**
- **132 patients enrolled in phase 2 to-date – Company is targeting 400 participants**
- **Aim of Phase 2 trial is to detect the likelihood of a current major depressive episode (cMDE) in individuals referred to a sleep clinic for PSG assessment using TRI's innovative AI-backed algorithm**
- **Trial progressing well and remains on track to complete in H1 CY2024 – TrivarX to concurrently progress discussions with US FDA regarding regulatory pathway**

**Perth, Australia, and Minneapolis, USA: TrivarX Limited** ('the **Company'**) (ASX: TRI) is pleased to advise that it completed on-boarding with a total of 15 sleep centres across the US to accelerate its phase 2 Sleep Signal Analysis for Current Major Depressive Episode study (SAMDE). 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.

Completion of on-boarding follows considerable in-bound interest from industry participants since the launch of phase 2 in September 2023 (refer ASX announcement: 4 September 2023). This included enquiries from Texas-based Comprehensive Sleep Medicine Associates ("CSMA") which added three additional sites and took the total number of centres being utilised in the trial to 15, exceeding TrivarX's initial target of 14. The Company is confident that it will complete phase 2 testing during H1 CY2024.

Trivarx is seeking to test 400 patients during phase 2, which will see clinicians administer a Mini International Neuropsychiatric Interview (MINI) for each trial subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding cMDE status. To date, the Company has successfully enrolled 132 of the 400 target patients.

Commencement of Phase 2 follows promising initial results from the first phase trial, generated from 313 participants, tested through 12 sleep centres across five states in the US.

The preliminary results from sleep data collected during phase 1 indicated algorithm sensitivity of 71.65%, specificity of 71.43%, Positive Predictive Value of 35.38%, and Negative Predictive Value of 92.11% when tested within the development sample with a cross-validation protocol (refer table below).

Preliminary Sensitivity results are promising with reference to current US industry standards, where data compiled by Kaiser Permanente for the US Department of Health & Human Services[i] for clinician recognition of depression ranges from 21% to 76% of cases. Around 50% of these estimates fall above and the remainder fall below the international pooled average of 47.3%. Other studies have also reported a sensitivity of 49.3% and specificity of 81.1% for US primary care providers in accurately identifying cMDE.

| Measure | Description | TRI preliminary result | Current standard of care |
|---|---|---|---|
| Sensitivity | Ability for the test to correctly identify patients with the disease | **71.65%** | 49.3% |
| Specificity | Ability to designate an individual who does not have the disease as negative | **71.43%** | 81.1% |
| Positive Predictive Value | Likelihood that a person who has a positive test result does have the disease or condition. | **35.38%** | NA |
| Negative Predictive Value | Likelihood that an individual with a negative test result does not have the disease or condition | **92.11%** | NA |

The Company continues to focus on patient enrolment, particularly in collaboration with Comprehensive Sleep Medicine Associates and will provide additional updates on milestones in the near term.

**Management commentary:**

**Comprehensive Sleep Medicines Associates, PA, Director and CEO, Jerald H, Simmons MD, Neurologist and Sleep Medicine Specialist, said:** *"Having an automated analysis of sleep data that can prove to be predictive of current major depression could help drive those in need to obtain proper interventions to improve their condition. We know there is extensive overlap between sleep disorders and psychiatric illness such as depression and I am glad that Comprehensive Sleep Medicine Associates is able to participate in this study to help Trivarx achieve its goals."*

**Non-executive Chairman, David Trimboli said:** *"TrivarX has made very pleasing progress in a short period in relation to phase 2 of its SAMDE trial and the on-boarding of an additional three sites with CSMA is expected to considerably fast track the initiative."*

*"Phase 2 will provide the Company with exceptional insight into how potentially valuable its innovative algorithm can be as a diagnostic screening tool. Results will also form the basis on Trivarx's engagement with the FDA to unlock a regulatory pathway for our product, ahead of commercial roll out.*

*"The Company's focus remains on increasing patient enrolment over the coming weeks to achieve our target quota of 400 participants. We look forward to continuing our work with CSMA and the 12 other centres that have been on-boarded for the trial to achieve this."*

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

**ENDS**

# ASX ANNOUNCEMENT



**Investor Enquiries:**

investors@trivarx.com
+61 8 6189 1155

Henry Jordan – Six Degrees Investor Relations
Henry.jordan@sdir.com.au
+61 431 271 538

**About TrivarX Limited:**

TrivarX (ASX: TRI) (OTCPINK: MDBIF) is a health technology company developing AI-driven, scientifically-based devices for screening and diagnosis of behavioral 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

[i] Screening for Depression in Adults: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force. Prepared by: Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2016, for the Agency for Healthcare Research and Quality, (U.S. Department of Health and Human Services).