ASX ANNOUNCEMENT

28 January 2025

Positive engagement with FDA following pre-submission meeting for MEB-001

Highlights:

- **Meeting provided TRI with confidence on clinical trial design for planned pivotal trial of MEB-001 prior to formal regulatory submission**
- **MEB-001 is TRI's innovative proprietary algorithm that assists in screening of current Major Depressive Episode (cMDE) using data obtained from in-clinic sleep studies**
- **The algorithm has been previously validated in the Company's Phase 2 Sleep Signal Analysis for cMDE trial which delivered promising algorithm performance metrics**
- **Engagement with prominent hospitals and sleep centres for pivotal trial advancing – collaborations expected to unlock access to high volume sites**
- **Site selection process underway with potential counterparties**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to provide the following update on the Company's pre-submission meeting with the United States (US) Food and Drug Administration (FDA) regarding its pivotal study design and clearance route for MEB-001.

MEB-001 is TrivarX's innovative, AI-backed algorithm that assists with screening of mental health conditions in sleep study patients. MEB-001 uses AI and machine learning capabilities to extract and analyse biometric data, EEG (brain), ECG (heart rate), and heart rate variability signals attained from in-clinic sleep studies to screen and aid in the diagnosis of current Major Depressive Episode (cMDE). In the Company's 400 patient Phase 2 trial, MEB-001 achieved a sensitivity of 87% and specificity of 72% (refer ASX announcement: 30 July 2024).

The Company advises that its most recent meeting with the US FDA has provided clear validation of TrivarX's proposed study design for the upcoming pivotal trial.

The trial utilises an adaptive design, allowing for interim data analysis, and plans to recruit a minimum of 563 patients from at least 5 study sites across the US. The primary inclusion criteria will be patients between 22 years and 75 years of age who have been referred to a sleep clinic for sleep disturbances. MEB-001 will be compared to the clinically-administered fully structured MINI Module A (incorporating Module O by reference) which was confirmed in the pre-submission meeting as a gold standard diagnosis of cMDE.

This trial is the final requirement before TrivarX can submit MEB-001 for FDA approval via the De Novo pathway. The Company is now progressing discussions with several prominent US sleep centres and hospitals to determine key study sites. Engagement with these groups is well advanced and is anticipated to unlock a number of high-volume locations for the trial.

Management commentary:

Non-executive Chairman, David Trimboli said: *"Recent positive engagement with the FDA has given the Company considerable confidence in its clinical development and regulatory pathway for MEB-001.*

"The Company continues to witness very pleasing interest from industry participants around collaboration for the trial. This has allowed management to advance discussions with a number of prominent groups which is expected to unlock a number of high-volume patient sites. We look forward to providing further updates on these initiatives as agreements materialise and key locations are determined."

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

ENDS

Investor Enquiries:

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 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