ASX ANNOUNCEMENT

24 September 2024

TrivarX Requests Pre-Submission Meeting with US FDA For Upcoming Pivotal Trial

Highlights:

- **Meeting request lodged following successful results from Phase 2 SAMDE study for TrivarX's proprietary AI-backed MEB-001 algorithm which assists with the effective screening of a current Major Depressive Episode (cMDE)**
- **Meeting with FDA expected to finalise pivotal clinical trial protocol, which will mark the final step before submitting to the FDA under the De Novo pathway**
- **Pre-submission meeting anticipated next quarter and pending required approvals, planned pivotal trial to commence shortly thereafter**
- **Recent Phase 2 results have led to considerable interest from leading, high-volume sleep centres across the US**
- **Onboarding for clinical sites for the pivotal trial expected to commence shortly**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to advise that it has submitted a formal request to the US Food & Drug Administration (FDA) for a pre-submission meeting to approve the design for a proposed pivotal trial which will test its proprietary AI-driven algorithm MEB-001. MEB-001 can greatly assist with the effective screening of current Major Depressive Episode (cMDE). There is currently no clinically-backed screening solution for cMDE utilised by sleep centers in the US or globally.

The request follows from the Company's successful Phase 2 SAMDE study, which demonstrated the effectiveness of MEB-001 in screening for cMDE – a condition which is commonly under or misdiagnosed (*refer ASX Announcement 30 July 2024*).

Following the successful results of the Phase 2 SAMDE Study, TrivarX is proceeding to a pivotal trial to confirm the effectiveness of the MEB-001 algorithm in screening for a cMDE. After multiple productive pre-submission meetings with the FDA, this next FDA meeting is expected to finalise the clinical trial protocol for the pivotal trial. This trial is the final requirement before TrivarX can submit MEB-001 for FDA approval via the De Novo pathway.

The Company expects to undertake the meeting with the FDA next quarter. Upon completion of the pre-submission meeting, TrivarX plans to commence the pivotal trial, aiming for an FDA submission in H1 CY2025.

Following the Phase 2 results, several prominent US sleep centers and research organisations have expressed interest in collaborating on the pivotal trial. These partnerships will help fast-track the trial's completion at high-volume sites.

Non-executive Chairman, David Trimboli said: *"Today's announcement marks the next step forward in our clinical development pathway, which is advancing well in close consultation with the FDA and our research partners.*

"We are working closely with the FDA to finalise the pivotal trial protocol, which will be very similar to the Company's Phase 2 SAMDE trial, to test the effectiveness of MEB-001 in improved screening for a current Major Depressive Episode (cMDE). This pivotal trial will be our final clinical step before FDA submission, bringing us closer to commercialising MEB-001.

"We are excited about the potential of MEB-001 to drive significant positive health outcomes. We look forward to providing more updates heading into the coming months as TrivarX continues to execute on our clinical development strategy."

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