BlinkLab Expands U.S. Clinical Trial Network: University of Nebraska Medical Center Engaged as Second Site in Main Phase of FDA 510(k) Study

Highlights:

- **Second U.S. Site Confirmed:** BlinkLab has selected the University of Nebraska Medical Center (UNMC) as the second clinical research site for the main phase of its FDA 510(k) diagnostic trial for autism.

- **Recognized Clinical Research Institution:** UNMC offers deep clinical trial expertise, access to specialized patient cohorts, and a history and track record of contributing to pivotal research programs.

- **Pilot Phase Nearing Completion:** BlinkLab's 100-participant pilot phase is progressing well, with results expected this quarter.

- **Main Study Phase Expanding:** Following the pilot, the main phase will enroll an additional 750–900 children across multiple U.S. sites.

- **Multi-Site Recruitment Strategy:** BlinkLab is targeting a total of up to 10 clinical sites across the U.S. during the main phase of the study to ensure geographic diversity, accelerate recruitment, and support broader clinical adoption of BlinkLab Dx 1 post-clearance.

- **Next Steps:** Site activation at UNMC is underway, with participant testing anticipated shortly after completion of the pilot phase.

BlinkLab Limited (ASX:BB1) ("BlinkLab" or "the Company") is pleased to announce the engagement of the University of Nebraska Medical Center (UNMC) as a key clinical partner in the main study phase of its pivotal U.S. FDA 510(k) diagnostic trial for BlinkLab Dx 1, a smartphone-based digital tool designed to aid in the early identification of autism spectrum disorder in children.

UNMC was selected for its strong clinical infrastructure, proven track record in multi-site research, and its capacity to deliver high-quality trial execution across diverse pediatric populations. As BlinkLab prepares to conclude its 100-participant pilot phase, the onboarding of additional sites ensures continuity and momentum as the trial transitions into the full-scale main phase.

Dr. Henk-Jan Boele, Co-founder and CEO of BlinkLab, commented:

"We're very pleased to welcome UNMC into our growing U.S. trial network. Their clinical research strength and access to diverse patient populations will help us ensure this study generates high-quality, generalizable data. Expanding to 10 sites, including institutions like UNMC, supports our strategy not just for regulatory clearance but for long-term clinical adoption."

Chairman of BlinkLab, Mr. Brian Leedman, added:

"Insights gained from the ongoing pilot phase have helped us optimize both our protocol and user experience. Expanding to a broader trial network during the main phase of the study will allow us to validate the technology in a range of real-world settings and diverse population which is critical for FDA clearance and future uptake by clinicians."

UNMC becomes the second of up to ten planned U.S. sites participating in the main study phase. This distributed trial structure is key to ensuring a diverse, representative sample of participants and building the foundation for national deployment of the BlinkLab Dx 1 platform following regulatory clearance.

The Company expects to submit its final FDA 510(k) application during 2026.

This announcement has been approved by the Board of Directors.

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About BlinkLab Limited (ASX:BB1)

BlinkLab Limited, a company founded by neuroscientists at Princeton University, over the past several years has fully developed a smartphone based diagnostic platform for autism, ADHD, schizophrenia, and other neurodevelopmental conditions. Our most advanced product is an autism diagnostic test that leverages the power of smartphones, AI and machine learning to deliver screening tests specifically designed for children as young as 18 months old. This marks a significant advancement, considering traditional diagnoses typically occur around five years of age, often missing the crucial early window for effective intervention. BlinkLab is led by an experienced management team and directors with a proven track record in building companies and vast knowledge in digital healthcare, computer vision, AI and machine learning. Our Scientific Advisory Board consists of leading experts in the field of autism and brain development allowing us to bridge most advanced technological innovations with groundbreaking scientific research.