blinklab

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BlinkLab Commences U.S. Autism Diagnostic Study with First Child Tested

- **BlinkLab's first patient has now been tested at PriMED Clinical Research LLC, officially launching the U.S. clinical trial.**
- **The study aims to validate BlinkLab Dx 1 as a critical diagnostic aid for clinicians in early assessment of developmental disorders.**
- **Together with North Shore Pediatric Therapy, PriMED will participate in the initial 100-participant study, with data expected to be released in Q3 2025. Following this phase, the clinical trial will proceed to the main study, aiming to enroll an additional 750-900 children.**
- **Final FDA 510(k) submission is expected at the end of CY2025.**

BlinkLab Limited (ASX:BB1) (**"BlinkLab"**, or the **"Company"**), a leading digital healthcare innovator, is pleased to announce the successful completion of the first patient tested in its pivotal U.S. autism diagnostic study. The initial testing took place at PriMED Clinical Research LLC ("PriMED") in Dayton, Ohio, officially marking the commencement of the largest digital diagnostic trial for autism in the United States.

The study's primary objective is to validate the BlinkLab Dx1 test as a diagnostic aid for clinicians. The AI-powered, smartphone-based neurological assessment is designed to provide parents and practitioners with a rapid and accurate tool to support the early detection of developmental conditions like autism, helping to improve long-term outcomes.

PriMED Clinical Research, a PriMED Physicians research company, was the first[1] of two[2] clinical sites announced that have been selected for the initial 100-patient phase of the study, with further patient enrolments for the main study expected to ramp up in the coming weeks.

Addressing an Urgent Medical Need

The American Academy of Pediatrics (AAP) advises that all children are screened for autism at the ages of 18 and 24 months, along with all regular developmental surveillance. Where there are indications of a heightened risk of developmental disorders, including autism and ADHD, it is advised that toddlers and children are then referred for further diagnostic

[1] ASX Announcement (5 February 2025) – *"BlinkLab Initiates its First US-based Clinical Site for Autism Diagnostic Registrational Trial"*

[2] ASX Announcement (10 February 2025) – *"North Shore Pediatric Therapy in Chicago Joins BlinkLab's US Registrational Study"*

evaluation. Additionally, it is advised that developmental delays which are identified should be addressed with early intervention options as soon as possible, and at the time of identification, rather than awaiting formal evaluations.

Despite these guidelines, many children experience delays in diagnosis for such conditions, missing critical windows for early intervention options, such as behavioural and developmental therapies, social skill training, occupational therapy, or pharmacological intervention if needed. BlinkLab's AI-powered solution aims to address this critical gap, enabling healthcare providers with the ability to deliver faster and more reliable autism assessments during crucial developmental stages in early childhood.

Pathway to Regulatory Clearance

The results of this pivotal study will form the foundation of BlinkLab's submission for FDA 510(k) clearance, which is anticipated in CY2026. This regulatory milestone is expected to pave the way for the Company's market entry in the United States and help to bridge the current diagnostic gap that currently exists for identifying developmental conditions like autism. BlinkLab's technology aims to provide families with accessible, efficient diagnostic solutions during the critical developmental windows for early intervention.

Crystal Jackson, Certified Clinical Research Coordinator and Site Manager for PriMED Clinical Research, stated: *"Dr. Rogelio Amisola, Principal Investigator and PCR's team of dedicated investigators & coordinators are thrilled to be the first U.S. site to screen participants in this monumental milestone for BlinkLab. We are hopeful our quality of data will assist BlinkLab Dx in advancing their AI technology to support medical professionals in the early detection of autism—bringing innovation and hope to families everywhere!"*

Dr. Henk-Jan Boele, Cofounder and CEO of BlinkLab, commented: *"Launching our U.S. trial marks a very special and important moment for BlinkLab. Our mission has always been to connect fundamental neuroscience with clinical practice through accessible technology, thereby enhancing autism diagnostic evaluations and enabling early intervention for children. After extensive app and portal development, stimulus refinement, and testing in hundreds of children, we are very confident in our FDA study's potential. I truly believe that this is a transformative moment. Early diagnosis is life-changing, and BlinkLab is dedicated to empowering families and healthcare providers with AI-driven tools for accurate, accessible, and timely autism assessments."*

This announcement has been approved by the Board of Directors.

For further information please contact:

Dr Henk-Jan Boele	Brian Leedman
Chief Executive Officer	Non-Executive Chairman
henkjan@blinklab.org	brian@blinklab.org
+31 (0) 611 132 247	+61 (0) 412 281 780

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.

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