blinklab

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# Positive Outcome from FDA Pre-Submission Meeting

***BlinkLab Achieves Pivotal Step Towards FDA Approval for Autism Diagnostic App***

## Highlights

- **Positive outcome received from a Pre-Submission meeting with the U.S. Food and Drug Administration ("FDA") regarding the regulatory pathway for BlinkLab Dx 1 diagnostic app.**

- **The FDA has confirmed the design for the BlinkLab Dx 1 registrational program, which will consist of an Initial Study Phase that then transitions into the Main Study. The Initial Phase will recruit up to 100 children with the main registrational study up to 1,000 subjects recruited from up to ten clinical sites.**

- **Several leading clinical sites across the U.S. have already been selected with ethics submission and site activation in process.**

- **The initial phase (of 100 children) will be used to:**
  - **Familiarise the investigators and personnel at clinical sites.**
  - **Train in-person and virtual recruitment strategies.**
  - **Test the procedures of subjects screening and data collection.**

- **These steps are part of the Company's strategy to de-risk the main FDA registrational study and to ensure the highest quality of the data collected and diagnostic accuracy of the BlinkLab App.**

- **FDA has confirmed the study protocol, statistical analysis plan, clinical endpoints and final data requirements to achieve 510(k) clearance for "BlinkLab Dx 1" as an aid in the diagnosis of autism.**

BlinkLab Limited (**ASX:BB1**) (**"BlinkLab"**, or the **"Company"**), an innovative digital healthcare company is pleased to announce a positive outcome from its Pre-Submission meeting with the FDA yesterday. The FDA has confirmed the study design and data requirements in order to achieve 510(k) clearance and subsequently launch the diagnostic app in the U.S. The Company plans to complete both programs within 12-16 months after the necessary approvals and site engagements have been secured.

**U.S. FDA registrational study in Autism Underway**

To support its FDA registration in the US, BlinkLab has initiated a large clinical study in children with autism. The goal of the study is to obtain FDA 510(k) clearance for BlinkLab Dx 1 to serve as a digital diagnostic aid for autism. BlinkLab has received positive feedback from the FDA on final clinical study design and data requirements in order to achieve FDA 510(k) clearance. Clinical site selection is in progress with ethics approvals and onboarding about to be complete for several sites.

The upcoming clinical program will consist of an Initial Study Phase that will precede the main registrational study. The Initial Study Phase will enrol 100 subjects with the main study continuing recruitment of up to 1,000 children with autism aged 2-11 years old. The FDA trial will involve leading clinical and research sites across the US, ensuring a diverse population of children in terms of race, ethnicity and gender. BlinkLab plans to complete both programs within 12-16 months after the necessary approvals and site engagements have been secured. This dual study approach ensures that clinical experts on sites as well as families participating in the study are fully trained and familiar with the BlinkLab Dx 1 diagnostic application and its functionalities.

Both phases of the study will incorporate a prospective, double-blinded, within-subject comparison design in order to establish BlinkLab's diagnostic accuracy. This will involve comparing BlinkLab Dx 1 output to the DSM-5 based diagnostic standards. Following completion of the study, should data meet the accuracy outputs, BlinkLab will submit the study report and supporting documentation for FDA 510(k) clearance in order to gain access to the U.S. autism diagnostic market.

**Brian Leedman, Chairman of BlinkLab commented on the milestone:** "This pivotal outcome in our FDA regulatory study process marks a significant milestone in our achievements as a listed Company. With this guidance from the Pre-Submission Meeting, we are confident in our study design and ability to bring BlinkLab Dx1 to market. We look forward to updating the market in early 2025 as to our progress in site selection, recruitment and results of the initial study".

**Henk-Jan Boele, CEO BlinkLab, commented:** "I am pleased that we had such a productive discussion with the FDA regarding our regulatory trial. Truly appreciate their support and alignment on addressing the unmet medical need. We look forward to collaborating closely with the FDA on advancing BlinkLab Dx 1."

The Board of Directors has approved this announcement.

**For further information, please contact:**

Dr. Henk-Jan Boele
Chief Executive Officer
henkjan@blinklab.org
M: +31 (0) 611 132 247

Brian Leedman
Non-Executive Chairman
brian@blinklab.org
M +61 (0) 412 281 780

**About BlinkLab Limited**

BlinkLab, a company founded by neuroscientists at Princeton University, over the past several years has fully developed a smartphone based diagnostic platform for autism, ADHD, and other neuropsychiatric conditions. BlinkLab's most advanced product is an autism diagnostic test that leverages the power of smartphones, neuroscience and AI to deliver screening tests specifically designed for young children. 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 neuroscience, 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 the most advanced technological innovations with groundbreaking scientific research.