RNS Number : 4165X
Cambridge Cognition Holdings PLC
18 February 2025

18 February 2025

Cambridge Cognition Holdings plc

("Cambridge Cognition", the "Company" or the "Group")

Cambridge Cognition submits FDA Letter of Intent for Cognitive Impairment Assessments in Schizophrenia

Cambridge Cognition (AIM: COG), the brain health software group specialising in digital products to advance clinical research and patient treatment, has submitted a Letter of Intent to the U.S. Food and Drug Administration (FDA) under the Drug Development Tool pathway, outlining its plan to develop and validate an objective and reliable measure of cognitive impairment associated with schizophrenia (CIAS).

The FDA has indicated that CIAS improvement could serve as a co-primary outcome in schizophrenia clinical trials, alongside functional improvement[1]. This development aligns with the growing recognition of cognitive symptoms as a crucial treatment target in schizophrenia care.

CIAS affects functions such as memory, attention, and problem-solving in people with schizophrenia. It appears early in the illness, even before medication starts. The impairment is typically more severe than cognitive issues seen in other mental health conditions and impacts daily functioning; making it harder for patients to work, maintain relationships, and live independently. Research shows that CIAS accounts for up to 60% of functional challenges faced by patients[2]. Unlike other schizophrenia symptoms, CIAS tends to persist regardless of whether other symptoms are well-controlled and there is no approved treatment which targets this important symptom.

The Letter of Intent outlines Cambridge Cognition's proposed approach to digital cognitive assessment for use in clinical trials in CIAS, making use of its touch screen computerised cognitive tasks and providing scalable assessments of the core cognitive domains affected in schizophrenia, reducing some of the burden associated with lengthy and potentially less accurate pencil and paper cognitive tests. The approach builds on recent positive exploratory results using several of these assessments in a Phase III clinical trial of patients with schizophrenia[3].

Rob Baker, Joint Managing Director and Chief Operating Officer, commented:

"This Letter of Intent submission to the FDA marks a pivotal moment in our strategy to address the critical need for improved cognitive assessment in schizophrenia. If approved, this holds the potential to streamline clinical trials and accelerate the development of targeted treatments. Our approach offers unique advantages in terms of sensitivity, reliability and ease of use compared to traditional cognitive assessment methods. While we are still in the early stages of this regulatory process, we are confident that our extensive scientific foundation and clinical evidence base position us well for constructive discussions with the FDA."

The Company will provide further updates as appropriate.

1. Keefe RS, Haig GM, Marder SR, Harvey PD, Dunayevich E, Medalia A, Davidson M, Lombardo I, Bowie CR, Buchanan RW, Bugarski-Kirola D. Report on ISCTM consensus meeting on clinical assessment of response to treatment of cognitive impairment in schizophrenia. Schizophrenia bulletin. 2016 Jan 1;42(1):19-33
2. Barnett JH, Robbins TW, Leeson VC, Sahakian BJ, Joyce EM, Blackwell AD. Assessing cognitive function in clinical trials of schizophrenia. Neuroscience & Biobehavioral Reviews. 2010 Jul 1;34(8):1161-77
3. Horan, William P., et al. "The Impact of Xanomeline and Trospium Chloride on Cognitive Impairment in Acute Schizophrenia: Replication in Pooled Data From Two Phase 3 Trials." American Journal of Psychiatry (2024).

Enquiries:

Cambridge Cognition Holdings plc Rob Baker, Chief Operating Officer and Joint Managing Director	**Tel: 012 2381 0700**
Panmure Liberum Limited (NOMAD and Joint Broker) Freddy Crossley / Will Goode / Mark Rogers Rupert Dearden	**Tel: 020 7886 2968** **(Corporate Finance)** **(Corporate Broking)**
Dowgate Capital Limited (Joint Broker) David Poutney / James Serjeant	**Tel: 020 3903 7715**
Hudson Sandler (Financial PR and IR) Dan de Belder / Hattie Dreyfus / Harry Griffiths	**Tel: 020 7796 4133** **cog@hudsonsandler.com**

Notes to Editors

Notes to Editors

About Cambridge Cognition

Cambridge Cognition is a brain health software group specializing in digital health products that advance brain health research and treatment.

The company offers four core products: CANTAB® assessments-providing scientifically validated, highly sensitive, precise, and objective measures of cognitive function correlated to neural networks; a flexible and proven eCOA platform with an extensive library of instruments, enabling efficient study setup and scalable data capture; rater training services that standardise assessment delivery and scoring across clinical trials and quality assurance tools that ensure data integrity by automatically detecting deviations in administration and scoring, saving time and money. These products collectively improve clinical trial outcomes, enable early patient identification, and enhance global efficiency in healthcare and pharmaceuticals.

For further information, visit: www.cambridgecognition.com

END

NRAMZGMZNNMGKZM