Oxford Brain Diagnostics awarded FDA Breakthrough Device Designation for technology to predict Alzheimer's Disease

Oxford, United Kingdom, 30 September 2020 – Oxford Brain Diagnostics Ltd, a spinout from the University of Oxford specialising in the measurement of neurodegeneration in Alzheimer's disease, today announces that the US Food and Drug Administration (FDA) has awarded Breakthrough Device Designation to its Cortical Disarray Measurement (CDM®) Software Device for evaluating adults at risk of Alzheimer's disease

Oxford Brain Diagnostics' first product from its software platform seeks to be a breakthrough in the evaluation of adult patients with Mild Cognitive Impairment (MCI) who are being evaluated for Alzheimer's disease. The CDM Software Device, used as an adjunct to other diagnostic evaluations, is intended to predict conversion from MCI to Alzheimer's disease in patients previously diagnosed with MCI. CDM technology uses non-invasive MRI brain scan data linked to changes in the brain at a cellular level, offering sensitive and accurate assessment of the neurodegeneration associated with Alzheimer's disease and other dementias.

The Breakthrough Device Program was established by the FDA to provide patients and healthcare providers with timely access to transformative medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket review and authorisation. Eligibility is restricted to innovative medical devices that provide more effective treatment or diagnosis of life-threatening conditions, where there are no approved or cleared alternatives, and where early device availability is in the best interests of patients.

Dr Steven Chance, CEO & Co-Founder said, 'We are very excited to be granted this designation by the FDA. It reinforces the potential for CDM technology to be a gamechanger for the early clinical recognition of Alzheimer's disease. Today, there is a huge gap in diagnostic evaluations, between early indicators of uncertain risk and definitive pathology at the end of life. This is not ideal in supporting patients and families living with this terrible condition. CDM hopes to solve this problem, enabling greater diagnostic certainty at the earliest opportunity by targeting the cellular structure of the brain, where the disease first materialises in the grey matter of the cortex. Our new software tool, powered by CDM analysis, intends to help clinicians predict which MCI patients will develop clear Alzheimer's disease and which patients will remain stable for years and need not worry unnecessarily."

Andrew Barker, Chairman said, "Dementia is one of the greatest healthcare challenges today. Around 50 million people worldwide have the disease, there are nearly 10 million new cases every year, and yet clinicians lack a method for early and accurate diagnosis. We aim to fill this gap in the fight against Alzheimer's with our ground-breaking CDM Software Device, and the FDA's Breakthrough Device designation will help us to bring it to market sooner by giving us a prioritised FDA review when we make our regulatory submission."

Oxford Brain Diagnostics Ltd is a spinout company from the University of Oxford that is developing diagnostic tools to enable early detection of disease, track progression, and support differential diagnosis of Alzheimer's disease using MRI brain scan data. The patent-protected **'Cortical Disarray Measurement' (CDM)** is a software-based technology that is designed to identify changes in the brain at a cellular level, enabling sensitive and accurate assessment of the neurodegeneration associated with Alzheimer's disease and other dementias. Oxford Brain Diagnostics' CDM software device aims to support drug development and aid clinicians around the world in their fight to defeat Alzheimer's disease.

For more information, visit https://www.oxfordbraindiagnostics.com