Quanterix Launches LucentAD Biomarker Blood Test to Aid Physician Diagnosis of Alzheimer's Disease in Patients

July 6, 2023

Test will play an important role in the evaluation of patients experiencing cognitive symptoms consistent with early signs of Alzheimer's disease

BILLERICA, Mass.--(BUSINESS WIRE)--Jul. 6, 2023-- Quanterix Corporation (NASDAQ: QTRX), a company fueling scientific discovery and breakthrough diagnostics through ultrasensitive biomarker detection, today announced it has launched LucentAD, a test to assist in the evaluation of patients experiencing cognitive symptoms consistent with the early signs of Alzheimer's disease (AD). The LucentAD test, which will be available to healthcare providers as an aid in conjunction with other diagnostic tools, provides clinicians with a simplified process to quickly assess the likelihood of a patient having amyloid pathology consistent with AD. This information will help healthcare providers determine appropriate follow up and treatment planning for a suspected Alzheimer's patient.

The LucentAD test is run by Quanterix's CLIA laboratory, which powers many of the clinical trials associated with AD. Lucent Diagnostics is Quanterix's new healthcare provider-facing portal, launched to meet the needs of patients at the same time a therapy for the disease has become more widely available. The test measures an isoform of phosphorylated tau protein in plasma. This isoform is phosphorylated at the 181 residue of the protein (p-Tau 181), and its concentration in plasma and cerebrospinal fluid, has been positively correlated to the presence of amyloid pathology in the brain, a hallmark of Alzheimer's disease. LucentAD utilizes the Simoa p-Tau 181 assay that has been extensively studied in large longitudinal and cross-sectional cohorts, and its high specificity for amyloid pathology for AD has been well established through comparison to amyloid positron emission tomography, a gold standard for AD diagnosis. p-Tau 181 is a low-abundance protein in blood, requiring high analytical sensitivity for its reliable measurement. While the clinical validity of Simoa plasma p-Tau 181 measurements have been well studied, the test has also recently been shown to correlate with reduction in amyloid load in the brains of amyloid patients on anti-amyloid drug therapy, as demonstrated in the lecanemab (Leqembi) Clarity AD drug trial.

"A year ago, Quanterix announced the validation of our laboratory developed test to quantitatively measure p-Tau 181 in plasma as an aid in diagnostic evaluation of Alzheimer's disease," said Masoud Toloue, CEO at Quanterix. "The launch of Lucent Diagnostics and availability of the LucentAD test expands access to our p-Tau 181 test for healthcare providers and marks an important step in our goal to help build a global Alzheimer's disease testing infrastructure."

The announcement of the LucentAD test comes at an exciting time for AD treatment and discovery, coupled with today's historic announcement FDA approval of Leqembi, the first disease-modifying drug for Alzheimer's to receive full approval. Earlier this year, Leqembi was granted accelerated approval by the FDA for the treatment of patients with early-stage AD, an important step forward in the fight against the disease, based on strong early clinical trial data. As detailed in the Leqembi labeling for accelerated approval, several biomarkers were used to track response to therapy, including plasma p-Tau 181, which was measured using Quanterix's Simoa® platform.

"The FDA's approval of Leqembi is an exciting day for families of the 55 million Alzheimer's patients globally," continued Toloue. "However, access to therapy will continue to be limited until the global infrastructure for patient testing is built. Non-invasive blood biomarker testing is the only way to democratize access to Alzheimer's disease therapies and Quanterix will offer our testing solutions to healthcare providers who want to provide this important service to patients."

"The clinicians working with dementia patients are viewing the coming of FDA-approved therapies for Alzheimer's disease with a mixture of excitement and anxiety, as the diagnostic paths to qualify patients for treatment in clinical practice are still inefficient in most clinics," said Tharick Pascoal, MD., Ph.D. Behavior Neurologist and Associate Professor of Psychiatry and Neurology at the University of Pittsburgh. "The availability of non-invasive blood tests to more efficiently identify patients for these treatments is an urgent need at a critical moment in the fight against this disease."

Lucent Diagnostics will announce additional tests aimed at improving the diagnosis and management of Alzheimer's and other neurological disorders. The LucentAD test is available through a healthcare provider's order.

To learn more about Lucent Diagnostics, visit: https://www.lucentdiagnostics.com/

For more information about Quanterix's work in neurology, visit: https://www.quanterix.com/therapeutic-areas/neurology/.

Disclaimer

The LucentAD test was developed and validated by Quanterix Corporation (CLIA# 22D1053083) in a manner consistent with CLIA requirements. The test has not been cleared or approved by the U.S. Food and Drug Administration.

The Lucent test measures tau protein phosphorylated at threonine 181. Circulating levels of p-Tau 181 have been shown to be a marker of Alzheimer's Disease (AD) pathology. The test results are intended as an aid in the diagnostic evaluation of AD, to be used in adults presenting with cognitive impairment who are being evaluated for AD. LucentAD test results must be interpreted in conjunction with other diagnostic tools. This test is not intended as a standalone screening or diagnostic assay.

About Quanterix

From discovery to diagnostics, Quanterix's ultrasensitive biomarker detection is fueling breakthroughs only made possible through its unparalleled sensitivity and flexibility. The Company's Simoa® technology has delivered the gold standard for earlier biomarker detection in blood, serum or plasma, with the ability to quantify proteins that are far lower than the Limit of Quantification (LoQ) of conventional analog methods. Its industry-leading

precision instruments, digital immunoassay technology and CLIA-certified Accelerator laboratory have supported research that advances disease understanding and management in neurology, oncology, immunology, cardiology and infectious disease. Quanterix has been a trusted partner of the scientific community for nearly two decades, powering research published in more than 2,000 peer-reviewed journals. Find additional information about the Billerica, Massachusetts-based company at https://www.quanterix.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release are based on Quanterix's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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