Quanterix
Discovery Fueled by Ultra-Sensitivity

Quanterix Granted Breakthrough Device Designation from U.S. FDA for Blood-Based p-Tau 217 Test for Alzheimer's Disease

March 4, 2024

March 4, 2024 - Quanterix Corporation (NASDAQ: QTRX), a leading provider of ultra-sensitive research products and high-definition diagnostics, announced today that its Simoa® phospho-Tau 217 (p-Tau 217) blood test has been granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA) as an aid in diagnostic evaluation of Alzheimer's Disease (AD). The FDA's Breakthrough Device designation is granted to products that have the potential to offer more effective diagnosis of life-threatening diseases with an unmet medical need.

p-Tau 217 has emerged as a top-performing biomarker for Alzheimer's pathology, with the Alzheimer's Association working group diagnostic criteria identifying p-Tau 217 as the only plasma biomarker appropriate for accurately diagnosing amyloid pathology. Given that traditional testing methods of positron emission tomography (PET) or lumbar puncture for cerebrospinal fluid (CSF) biomarkers are invasive and commonly inaccessible, high-performing blood-based biomarker tests may be an appropriate alternative for patient care. As a trailblazer in the AD biomarker field, Quanterix is dedicated to the development of ultrasensitive assay tests and enhancing clinical AD diagnostics through improved accessibility to blood biomarker tests.

"Early detection is crucial in shaping effective care strategies and improving patient outcomes," said Masoud Toloue, CEO of Quanterix. "The breakthrough designation is an important step in our strategy to develop a global testing infrastructure for Alzheimer's Disease. The FDA's decision to grant Breakthrough Device Designation further validates the importance of accessible, non-invasive p-Tau 217 testing."

The remarkable advancements in blood-based biomarkers made in AD research and diagnostics can be largely attributed to significant advancements in high sensitivity methods such as Quanterix's Simoa® technology, which paved the way with immunoassays for numerous blood-based biomarkers with potential diagnostic significance for Alzheimer's. The Simoa p-Tau 217 test described in the Breakthrough Device application is a semi-quantitative in vitro diagnostic immunoassay intended for the measurement of p-Tau 217 concentration in plasma using the Quanterix HD-X immunoassay system. Proposed indications include use of the test results in patients presenting with cognitive impairment who are being evaluated for AD risk to aid in diagnostic evaluation. The test is not intended as a stand-alone diagnostic test and test results will be interpreted in conjunction with other diagnostic tools to establish a final clinical diagnosis.

The Breakthrough Device designation for the p-Tau 217 test underscores its potential to significantly impact Alzheimer's disease (AD) diagnosis and treatment. However, Breakthrough Device designation does not guarantee that the FDA review and approval process will be shortened or that an application will be approved.

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

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 2,700 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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