Quanterix Granted Breakthrough Device Designation from U.S. FDA for Blood-Based pTau-181 Assay for Alzheimer's Disease

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BILLERICA, Mass.--(BUSINESS WIRE)--Oct. 11, 2021-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis with the goal of advancing the science of precision health, announced today that its Simoa® phospho-Tau 181 (pTau-181) 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. The program is designed to enable accelerated development, assessment and review processes, with the intention to provide patients with more timely access to breakthrough technologies or devices.

"Quanterix's technology has the unique ability to detect low-abundance markers in a blood sample, unlocking the possibility for earlier, more accessible, non-invasive diagnosis of disease, including AD. The breakthrough designation represents an important step in our long-term strategy to develop ultra-sensitive in vitro diagnostics," said Kevin Hrusovsky, Chairman and CEO, Quanterix Corporation. "More importantly, it further validates the potential of our ultrasensitive Simoa technology, and we remain deeply committed to leveraging our innovative platform to support advances in neurodegenerative research and the translation of breakthrough scientific discoveries into the clinic. Our Research Use Only assays, including our Simoa pTau-181 assay, remain important tools in supporting these advances."

The Simoa pTau-181 test is a semiquantitative immunoassay intended for the measurement of pTau-181 concentration in human serum and plasma using the Quanterix HD-X immunoassay system. Proposed indications under the Breakthrough Device designation include use of the test results in adult patients, aged 50 years and over, presenting with cognitive impairment who are being evaluated for AD and other causes of cognitive decline as an aid in diagnostic evaluation for AD. The test is not intended as a stand-alone diagnostic assay and test results will be interpreted in conjunction with other diagnostic tools to establish a final clinical diagnosis. Breakthrough Device designation does not guarantee that the FDA review and approval process will be shortened or that an application will be approved.

About Quanterix

Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa®, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease. The company was established in 2007 and is located in Billerica, Massachusetts. For additional information, please visit https://www.quanterix.com.

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' 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' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix' 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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