Quanterix Granted Breakthrough Device Designation from U.S. FDA for NfL Test for Multiple Sclerosis

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Blood-based assay has the potential to serve the multiple sclerosis (MS) community in management of relapsing-remitting form of the disease

BILLERICA, Mass.--(BUSINESS WIRE)--Apr. 22, 2022-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis with the goal of advancing the science of precision health, today announced that its Simoa® neurofilament light chain (NfL) plasma test has been granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA) as a prognostic aid in assessing the risk of disease activity in patients diagnosed with relapsing-remitting MS (RRMS). The FDA's Breakthrough Device designation is granted to products that have the potential to offer more effective diagnosis or treatment 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. However, Breakthrough Device designation does not guarantee that the FDA review and approval process will be shortened or that an application will be approved.

The Quanterix Simoa® NfL test is a digital immunoassay that quantitatively measures NfL in human serum and plasma and shows promise to be used in conjunction with clinical, imaging and laboratory findings as an aid in identifying RRMS patients who are at lower or higher risk for relapse within four years. This prognostic information could be useful in tailoring the therapeutic approach to more effectively treat the disease.

"For the more than two million people suffering from MS worldwide, there's an important need for more informed and effective treatment options," said Kevin Hrusovsky, Chairman and Chief Executive Officer, Quanterix and Founder of Powering Precision Health (PPH). "Obtaining FDA breakthrough device designation for our plasma NfL MS test was a key objective for 2022. We are pleased to have the opportunity to work with the FDA to help advance the Quanterix Simoa® NfL test towards regulatory approval."

The designation comes on the heels of a large-scale, international study published in *The Lancet Neurology*, in which researchers from the University Hospital Basel and University of Basel leveraged Quanterix' ultra-sensitive Simoa® technology to help establish a new method for clinicians to identify and interpret elevated values of sNfL in individual MS patients. Along with this research, the Simoa® NfL assay was referenced in at least 20 studies presented at the American Academy of Neurology (AAN) 74th Annual Meeting, further validating the biomarker's potential utility.

"There has been an ever-growing body of research with the Simoa® NfL blood test supporting NfL as a reliable biomarker for MS disease activity prognosis and treatment response monitoring," said Dr. Mark S. Freedman, Professor of Neurology and Director of Multiple Sclerosis Research at the Ottawa Hospital. "The FDA's grant of Breakthrough Device designation for this test has the potential to help the multiple sclerosis community further advance the optimal use of NfL measurements in both research and clinical practice aimed at more effective therapeutic management of the disease for the millions of patients suffering from the condition."

This is the second test from Quanterix to receive Breakthrough Device status – the company's phospho-Tau 181 (pTau-181) assay for Alzheimer's disease received the designation in 2021.

To learn more about Quanterix' Simoa® technology, visit: https://www.quanterix.com/technology.

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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