

Quanterix Expands Menu of Ultra-Sensitive Neurology Assays with Simoa® P-Tau181 V2 Kit for Improved Detection and Study of Alzheimer's Disease

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Preliminary research demonstrates the biomarker's revolutionary potential to empower accessible and scalable blood testing for Alzheimer's disease; Quanterix to discuss latest findings and how researchers can gain early access to newest Simoa assay during June 3 PPH webinar

BILLERICA, Mass.--(BUSINESS WIRE)--May 29, 2020-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis to advance the science of precision health, today announced that it will expand its robust menu of ready-to-use Simoa® kits to include tau phosphorylated at threonine 181 (p-tau181), a highly specific biomarker for the study of Alzheimer's disease pathology, in cerebral spinal fluid (CSF), serum and plasma. A growing body of research, including work published recently in *The Lancet Neurology*, suggests that the biomarker could prove critical to predicting Alzheimer's disease progression and differentiating the disease from other neurodegenerative disorders. Moreover, an ultrasensitive, blood p-tau181 assay may hold the key to advancing preventative care for the disease in clinics and via homecare sampling through a simple, cost-effective blood-based screening that can deliver an early, objective diagnosis. These findings and details on how researchers can gain early access to Quanterix' new commercial assay through the <u>Simoa Accelerator Laboratory</u>, will be discussed during an upcoming <u>Powering</u> <u>Precision Health (PPH)</u> Think Tank Webinar taking place at 10 a.m., EDT on June 3, 2020.

"Biomarkers continue to play an invaluable role in understanding how neurological diseases manifest, progress and respond to treatment," said Kevin Hrusovsky, Chairman, Chief Executive Officer and President, Quanterix. "Building on years of innovation and a proven track record for successfully commercializing ultra-sensitive assays that disrupt markets and drive innovative breakthroughs forward, our p-tau181 version 2 assay kit offers researchers unrivaled visibility and specificity into this revolutionary marker in serum and plasma. The exquisite sensitivity of Simoa uniquely positions us to deliver on the promise of p-tau181 to pave new pathways in Alzheimer's disease exploration, just as our <u>neurofilament light chain (Nf-L) assay</u> has transformed research for other neurological diseases. In particular, the impact of a high-definition, blood-based Simoa assay that rivals traditional CSF or PET scans could be revolutionary, with material potential for home sampling to enable early detection and development and approval of drug therapies desperately needed to improve outcomes for the millions of people living with Alzheimer's disease today. This biomarker advance fits perfectly in our vision to transform reactive 'sick care' into proactive asymptomatic precision healthcare."

While deaths associated with other pervasive diseases such as heart disease have declined between 2000 and 2018, Alzheimer's disease-related deaths have increased by 146 percent, according to the Alzheimer's Association. Importantly, there is no objective test to diagnose the disorder, leading many physicians to rely solely on subjective cognitive assessments. As a result, many patients are not diagnosed until late in the disease's progression, after symptoms of cognitive decline, such as memory loss, begin to present. Even then, the disease can often be misdiagnosed for another neurodegenerative condition, such as frontotemporal dementia (FTD).

For years, researchers have studied the utility of biomarkers for understanding, detecting and monitoring Alzheimer's disease. These efforts have been accelerated in large part by the PPH network, which has grown into a global epicenter for biomarker-enabled innovations to not only detect and treat, but ultimately, prevent disease. Resulting studies demonstrate the vast utility of proteins such as total tau and Nf-L. Researchers, doctors and pharmaceutical companies are now harnessing these biomarkers to see the disease earlier, monitor its progression and inform clinical decision making more effectively, and assess the viability of experimental therapies. Quanterix' ultra-sensitive immunoassay technology, Simoa, which empowers single- and multi-plex detection of key biomarkers with 1000 times greater sensitivity than competing enzyme-linked immunosorbent assay (ELISA) solutions, is the driving technology behind much of this research. Among the most notable is a 2019 *Nature Medicine* paper that used Simoa to see signs of Alzheimer's disease 16 years before symptoms through the high-definition detection of the disease with equal or greater sensitivity as compared to CSF or PET biomarkers. Collectively, these studies create an influential body of research that advances the preventative care paradigm envisioned by PPH at its inception by supporting the utility of a non-invasive and easily administered blood test to detect Alzheimer's disease before symptoms.

Today, emerging research suggests that p-tau181 could hold even greater diagnostic promise for Alzheimer's disease, as it has proven capable of differentiating the condition from other forms of dementia with greater specificity than total tau. Leaders in the field of neurodegenerative disease research, such as the authors of *The Lancet Neurology* paper Professors Henrik Zetterberg, MD, PhD, and Kaj Blennow, MD, PhD, of the University of Gothenburg, believe blood p-tau181 has the potential to revolutionize Alzheimer's disease research and patient care in much the same way that serum-based Nf-L has for multiple sclerosis (MS). These concepts further progress PPH's mission and vision to harness biomarkers for true precision health, with myriad implications that include improving understanding of the condition, enabling earlier diagnosis and intervention, informing more accurate long-term care, identifying clinical trial candidates earlier in the disease cascade and, subsequently, accelerating promising new therapies to market.

The latest installment of the PPH Think Tank series of webinars, entitled "Novel p-tau181 Blood Immunoassay and the Future of Alzheimer's Disease Research," will explore the vast opportunities associated with p-tau181 to revolutionize the way we approach disease and administer care. Specifically, the discussion will detail how an innovative immunoassay to measure p-tau181 in blood could accelerate efforts to establish a clinically relevant routine Alzheimer's disease diagnostic test, and the potential high-definition detection via small volume blood samples creates for homecare precision health. Hrusovsky, together with Professors Zetterberg and Blennow, will break down the findings from the recent paper in *The Lancet Neurology* and examine how Simoa is powering exploration into uncharted territory as it pertains to Alzheimer's disease detection, monitoring, treatment and prevention.

"We're on the cusp of what could be an incredible new era for Alzheimer's patients and those with a genetic predisposition to the disease," said Zetterberg. "The ability to see dementia asymptomatically and moreover conclusively distinguish it as Alzheimer's disease-induced could forever change the face of this condition. P-tau181 shows immense promise in this regard, which is augmented considerably when harnessed by a leader in detection like Quanterix."

"Early findings from our work with p-tau181 are very encouraging," said Blennow. "The biomarker is proving to be an exceptional new tool in our arsenal against Alzheimer's disease. While CSF p-tau181 has been recognized as a highly valuable biomarker in Alzheimer's disease pathology, the greater clinical benefit will come from our ability to effectively harness the marker in blood. The unprecedented specificity of p-tau181 paired with a highly sensitive technology like Simoa promises to broaden our knowledge of this devastating disease considerably, with monumental implications for patients and caregivers."

To register for the webinar, click here.

To learn more about how you can take advantage of our early access program for p-tau181 through the Accelerator Lab or pre-order your commercial kits, visit <u>https://www.guanterix.com</u>.

For more about Quanterix' Simoa® technology, visit https://www.quanterix.com/Simoa-bead-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.

About Powering Precision Health

Powering Precision Health is the world's first independent, non-profit organization dedicated to bringing the world's leading physicians, scientists, innovators, investors and patient advocates together to unveil their latest research on new biomarkers that are revolutionizing precision health. Founded by Kevin Hrusovsky, a widely acclaimed thought leader and visionary in life sciences and personalized medicine, Powering Precision Health is a movement that represents the intersection of new technological capabilities with the latest medical research. It's rooted in the science of precision medicine, which shows personalized treatments to be an increasingly more effective way to maximize drug efficacy and minimize toxicity. In addition to the impact environmental and lifestyle factors can have on minimizing disease triggers, precision health marks an evolution in the way we approach disease and aims to inspire a full healthcare transformation, from philosophy to approach to outcome. In an industry often plagued by skepticism and marred by false promises, PPH puts science first and brings together stakeholders that span from fundamental research to clinical practice, investors, policy makers, patient advocacy groups, and anyone who embraces the vision of Powering Precision Health. Featuring a distinguished keynote lineup of dignitaries, the Summit unveils groundbreaking approaches to prevention, early diagnosis, and next-generation treatments. Powering Precision Health is supported thanks to the generous contributions of sponsors from a wide range of companies and organizations committed to advancing precision health.

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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