Quanterix Announces FDA 510(k) Submission for a Multi-Analyte Algorithmic Blood Test for Alzheimer's Disease Detection

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Submission utilizes the comprehensive five-analyte panel and algorithm that formed the basis for Quanterix's LucentAD® Complete LDT

BILLERICA, Mass.--(BUSINESS WIRE)--Feb. 3, 2026-- **Quanterix Corporation (Nasdaq: QTRX)**, a company transforming healthcare by accelerating biomarker breakthroughs from discovery to diagnostics, today announced it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for a multi-analyte algorithmic blood test for Alzheimer's disease (AD). This submission represents a significant milestone in the Company's mission to provide superior, non-invasive, high-performance diagnostic tools to aid in the evaluation of patients with cognitive symptoms for possible AD. The multi-analyte test previously received Breakthrough Device Designation from the FDA, a program intended to accelerate the development and review of devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. The test is intended to aid in identifying whether patients with cognitive symptoms are likely to have amyloid brain plaques—a hallmark of Alzheimer's disease—providing diagnostic clarity through a non-invasive blood test.

The multi-analyte algorithmic blood test utilizes Quanterix's proprietary Simoa® technology to measure a panel of five key analytes: p-Tau 217, Aβ42, Aβ40, GFAP, and NfL. By integrating these AD-relevant biomarkers of amyloid pathology, tau pathology, neuroinflammation, and axonal damage into a single algorithmic result, the test provides a more comprehensive assessment of the biological drivers of Alzheimer's disease than single-analyte assays. This multi-analyte approach is designed to improve diagnostic clarity, particularly in the early stages of disease progression where single-analyte levels can often fall into an "intermediate" or inconclusive range.

The submission is supported by extensive clinical evidence recently published in *Alzheimer's & Dementia: Diagnosis, Assessment & Disease Monitoring* spanning three independent cohorts and over 1,800 symptomatic patients. Simoa digital sensitivity enables a quantitative test result for every patient, overcoming the sensitivity limitations often found in conventional analog immunoassay methods and mass spectrometry. Furthermore, the unique inclusion of multiplexed GFAP and NfL can enable potential differential and prognostic insights, extending patient risk evaluations beyond a static amyloid status readout as provided by p-Tau 217 and ratio tests.

"The strong execution of the Quanterix team has resulted in this submission, a watershed moment for Quanterix and millions of families seeking clearer answers in the fight against Alzheimer's disease," said Mike Miller, Chief Operating Officer of Quanterix. "Both research and extensive clinical validation evidence confirm that a comprehensive, multi-analyte panel is essential for capturing the complexity and trajectory of this disease. This filing is the next step in our strategy to establish our technology as a gold standard in clinical diagnostics, offering a scalable solution that bridges the gap between early detection and the emerging class of disease-modifying therapies."

About Quanterix

Quanterix is a global leader in ultra-sensitive biomarker detection, enabling breakthroughs in disease research, diagnostics, and drug development. Its proprietary Simoa® technology delivers industry-leading sensitivity, allowing researchers to detect and quantify biomarkers in blood and other fluids at concentrations far below traditional limits. With approximately 6,000 peer-reviewed publications, Quanterix has been a trusted partner to the scientific community for nearly two decades. In 2025, Quanterix acquired Akoya Biosciences, The Spatial Biology Company®, adding multiplexed tissue imaging with single-cell resolution to its portfolio and 1,396 installed instruments. Together, the combined company offers a uniquely integrated platform that connects biology across blood and tissue—advancing precision medicine from discovery to diagnostics. Learn more at 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'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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Quanterix Media Contact:
media@quanterix.com

Investor Relations Contact:
Joshua Young
(508) 846-3327 - mobile
jyoung@quanterix.com

Source: Quanterix Corporation