TETmedical™

FOR IMMEDIATE RELEASE

TETmedical Receives FDA Breakthrough Device Designation for NSE-FAST®, the First Rapid Test Designed to Aid in the Diagnosis of Acute Ischemic Stroke

Fair Haven, NJ, Ithaca, NY, June 22, 2026 — TETmedical, Inc., a clinical stage medical diagnostics company developing rapid tools for diagnosing acute neurological injury based on its patented Tethered Enzyme Technology (TET), today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to its NSE-FAST® (Neuron Specific Enolase — Functional Activity Stroke Test), a rapid in vitro diagnostic assay intended to aid in the diagnosis of acute ischemic stroke.

The designation was issued by the FDA's Center for Devices and Radiological Health (CDRH), Division of Immunology and Hematology Devices.

Stroke remains one of the leading causes of death and a major cause of long-term disability in the United States. Each year, approximately 840,000 Americans suffer an acute stroke, of which roughly 87 percent are ischemic, resulting from obstruction of blood flow to the brain.

An estimated 2.3 million patients present annually to emergency departments with neurological symptoms suggestive of stroke. While CT scans are highly effective at identifying hemorrhagic strokes, they frequently fail to detect acute ischemic strokes. A recent published study[1] reported that stroke is the number one clinical condition associated with serious misdiagnosis-related harms with an average of 17 percent of strokes missed.

NSE-FAST® is a rapid, enzyme-based luminescence assay that measures the functional enzymatic activity of Neuron Specific Enolase (NSE) in a patient's blood plasma. The test is intended for use with other available clinical information to aid in the diagnosis of acute ischemic stroke in adult patients. The NSE-FAST® utilizes TETmedical's patented Tethered Enzyme Technology to rapidly measure NSE functional activity as a biomarker for acute ischemic stroke.

The FDA Breakthrough Devices Program is intended to accelerate the development and review of medical devices that may provide for more effective diagnosis or treatment of life-threatening or irreversibly debilitating diseases or conditions where no approved alternatives exist. The designation provides TETmedical with prioritized access to FDA experts, enhanced opportunities for interactions with the agency, and the potential to efficiently align with clinical and regulatory requirements throughout the development process.

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[1] Newman-Toker, D., et al., *Comparative Effectiveness Review: Diagnostic Errors in the Emergency Department - A Systematic Review.* 2022, Agency for Healthcare Research and Quality (AHRQ). p. 1-128.

FDA Breakthrough Device Designation may also position NSE-FAST® for consideration under emerging FDA-CMS initiatives designed to reduce the time between FDA authorization and Medicare coverage decisions for eligible technologies. The program is known as Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway. Inclusion in such programs requires additional criteria and is not guaranteed.

> "This designation represents an important recognition of NSE-FAST® and its potential to address one of medicine's most significant unmet diagnostic needs," said **Dr. David Fischell, Co-Founder and Chief Executive Officer of TETmedical.**

> "Acute ischemic stroke remains the leading missed diagnosis causing serious harm in emergency medicine. We are gratified that the FDA has recognized the potential of the NSE-FAST® to help address this longstanding challenge. We are fortunate that the NSE-FAST® needs but a single additional small tube of blood collected under IRB approvals with a waiver of patient informed consent. We look forward to working closely with the agency as we advance the NSE-FAST® through our pivotal study toward our goal of bringing the first rapid blood test for ischemic stroke to patients and physicians."

TETmedical plans to initiate a multi-center pivotal study in the fourth quarter of 2026.

Subject to timely initiation of the study, TETmedical anticipates completing patient enrollment in the second half of 2027 and submitting its marketing application to the FDA by the fourth quarter of 2027.

Breakthrough Device Designation does not alter the statutory standards for marketing authorization under Section 510(k), 513(f)(2) or 515(c) of the Federal Food, Drug, and Cosmetic Act, and does not guarantee that a device will ultimately receive FDA authorization or clearance for marketing.

ABOUT TETMEDICAL, INC.

TETmedical is a medical diagnostics company focused on developing rapid, near-patient in vitro diagnostic tools for acute neurological injury. The Company's lead product, NSE-FAST®, is designed to measure the functional enzymatic activity of Neuron Specific Enolase in plasma as an aid in the diagnosis of acute ischemic stroke.

NSE-FAST® represents the lead program arising from TETmedical's patented Tethered Enzyme Technology platform, which the Company believes may have broader applications for diagnosis of acute neurological injury and other disease states.

On June 15, 2026, the FDA granted NSE-FAST® Breakthrough Device Designation. TETmedical plans to initiate its multi-center pivotal study in the fourth quarter of 2026.

For more information, please visit www.tetmedical.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, among others, the Company's plans to initiate a multi-center pivotal study in the fourth quarter of 2026, anticipated completion of patient enrollment in the second half of 2027, planned submission of its marketing application to the FDA by the fourth quarter of 2027, and the potential eligibility for future FDA-CMS initiative known as RAPID. Waived Patient Informed Consent while allowed under IRB approvals in the past are not guaranteed to continue for future clinical studies.

These statements are based on management's current expectations and assumptions and are subject to a number of risks and uncertainties, including the Company's ability to initiate and complete clinical studies on anticipated timelines, obtain required regulatory authorizations, secure adequate financing and satisfy criteria for any future reimbursement initiatives.

The FDA Breakthrough Device Designation does not guarantee that NSE-FAST® will ultimately receive FDA authorization, clearance, Medicare coverage, or commercial success. Actual results may differ materially from those expressed or implied in these forward-looking statements. TETmedical undertakes no obligation to update forward-looking statements, except as required by applicable law.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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Keywords

#Stroke #IschemicStroke #HemorrhagicStroke #BrainInjury #NeuronSpecificEnolase #PosteriorCirculation #AnteriorCirculation #NeurologicalImpairment #CerebralImaging