Tenaya Therapeutics Granted U.S. FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for TN-401 for the Treatment of PKP2-Associated Arrhythmogenic Right Ventricular Cardiomyopathy

September 14, 2026

RMAT Designation Supported by Positive Interim Data from RIDGE™-1 Phase 1b/2 Clinical Trial of TN-401 which Demonstrated Reduced Arrhythmia Burden

Additional Data and Updates on Regulatory Discussions Anticipated in 4Q 2026

SOUTH SAN FRANCISCO, Calif., Sept. 14, 2026 (GLOBE NEWSWIRE) -- Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a clinical-stage biotechnology company with a mission to discover, develop and deliver potentially curative therapies that address the underlying causes of heart disease, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to TN-401, Tenaya's gene therapy candidate for the treatment of *PKP2*-associated arrhythmogenic right ventricular cardiomyopathy (ARVC).

"RMAT designation underscores the continued recognition by regulators of the seriousness of *PKP2*-associated ARVC and the potential of TN-401 gene therapy to change the course of disease by addressing its underlying cause. This designation is supported by the encouraging interim data generated to date from our RIDGE-1 trial, which demonstrated clinically meaningful reductions in daily rates of PVCs and NSVTs, as well as a favorable tolerability profile," said Faraz Ali, Chief Executive Officer of Tenaya Therapeutics. "Together with Fast Track and Orphan Drug designations, RMAT enhances our ability to engage with the FDA as we strive to advance TN-401 toward a pivotal trial in order to bring this potentially transformative treatment to patients as quickly as possible. We look forward to sharing additional data from RIDGE-1 in the fourth quarter and providing an update on our ongoing discussions with regulators regarding pivotal trial plans for TN-401."

Tenaya's RMAT application included data presented at the American Society for Gene and Cell Therapy (ASGCT) Annual Meeting in May 2026. Interim results from the RIDGE-1 clinical trial of TN-401 showed improvements in multiple electrical stability measures, including reduced rates of premature ventricular contractions (PVCs) and non-sustained ventricular tachycardias (NSVTs), two of the most frequently occurring forms of ventricular arrhythmias that characterize ARVC.

RMAT designation is an FDA expedited program intended to facilitate the development and review of regenerative medicine therapies for serious conditions where preliminary clinical evidence indicates the potential to address unmet medical needs. RMAT designation provides enhanced opportunities for interaction with the FDA, including early and ongoing guidance regarding clinical development, manufacturing and potential regulatory pathways, and it may provide eligibility for accelerated approval, priority review and rolling review.

About *PKP2*-Associated ARVC

Plakophilin-2 (*PKP2*) mutations are the most common genetic cause of arrhythmogenic right ventricular cardiomyopathy (ARVC, also known as arrhythmogenic cardiomyopathy or ACM), occurring in approximately 40 percent of the overall ARVC population. The prevalence of *PKP2*-associated ARVC is estimated at more than 70,000 people in the U.S. alone.

In *PKP2*-associated ARVC, mutations of the *PKP2* gene results in insufficient expression of a protein needed for the proper functioning of the desmosomal complex that maintains physical connections and electrical signaling between heart muscle cells. As the desmosome structure degrades, cardiac muscle cells are replaced by fibrofatty tissue and electrical pulses in the heart become unstable, resulting in life potentially threatening heart rhythms. ARVC symptoms include arrhythmias, palpitations, lightheadedness, dizziness and fainting. It is typically diagnosed before age 40, and sudden cardiac arrest due to ventricular arrhythmia is frequently the first manifestation of disease. Current treatments include anti-arrhythmic medications, implantable cardioverter-defibrillators (ICDs) and ablation procedures, which do not address the underlying genetic cause of disease.

About TN-401 Gene Therapy and the RIDGE-1 Clinical Trial

TN-401 is an investigational AAV9-based gene therapy being developed for the treatment of ARVC due to mutations in the *PKP2* gene. AAV9 was selected as the vector for delivery of Tenaya's *PKP2* gene therapy based on its extensive clinical and commercial safety record and demonstrated ability to target heart muscle cells. TN-401 has received Orphan Drug and Fast Track Designations from the U.S. Food and Drug Administration, as well as PRIME designation from the European Medicines Agency. Tenaya's development of TN-401 is supported in part by a grant from the California Institute for Regenerative Medicine (CIRM).

The RIDGE-1 Phase 1b/2 clinical trial ClinicalTrials.gov (NCT06228924) of TN-401 in patients with *PKP2*-associated ARVC is a multi-center, open-label, dose escalation study being conducted in the U.S. and UK. RIDGE-1 is intended to assess the safety, tolerability and preliminary clinical efficacy of a one-time intravenous infusion of TN-401. RIDGE-1 seeks to enroll up to fifteen adults who have been diagnosed with *PKP2*-associated ARVC, have an ICD and are at increased risk for arrhythmias as determined by premature ventricular count (PVC) during screening. As part of its TN-401 development program, Tenaya is also conducting RIDGE ClinicalTrials.gov (NCT06311708), believed to be the largest natural history study of adults with *PKP2*-associated ARVC.

To learn more about gene therapy for ARVC and the RIDGE-1 clinical trial, please visit ARVCstudies.com.

About Tenaya Therapeutics

Tenaya Therapeutics is a clinical-stage biotechnology company committed to a bold mission: to discover, develop and deliver potentially curative therapies that address the underlying drivers of heart disease. Tenaya's pipeline includes clinical-stage candidates TN-201, a gene therapy for MYBPC3-associated hypertrophic cardiomyopathy (HCM); TN-401, a gene therapy for PKP2-associated arrhythmogenic right ventricular cardiomyopathy (ARVC); and TN-301, a highly specific small molecule HDAC6 inhibitor with broad potential clinical utility in cardiac, metabolic and muscular conditions, including heart failure with preserved ejection fraction (HFpEF) and Duchenne muscular dystrophy (DMD). Tenaya has employed a suite of integrated internal capabilities including modality agnostic target discovery and validation, to generate a portfolio of novel medicines based on genetic insights, aimed at the treatment of both rare genetic disorders and more prevalent heart conditions. For more information, visit www.tenayatherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Words such as "anticipated," "potential," "strive," "look forward," "may" and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, the plan and related timing to share additional data from RIDGE-1 and provide an update on regulatory discussions regarding pivotal trial plans for TN-401; the potential for TN-401 gene therapy to change the course of *PKP2*-associated ARVC by addressing the underlying cause of disease; the potential development and regulatory review opportunities for TN-401 due to RMAT designation; Tenaya's efforts to advance TN-401 toward a pivotal trial; and statements by Tenaya's Chief Executive Officer. The forward-looking statements contained herein are based upon Tenaya's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including but not limited to: availability of data at the referenced time; the timing and progress of RIDGE-1 and Tenaya's other ongoing clinical trials; the potential failure of TN-401 and Tenaya's other product candidates to demonstrate safety and/or efficacy in clinical testing; the potential for the FDA and/or other regulatory agencies to conclude at any time that TN-401 may not have an appropriate risk/benefit profile; changes in Tenaya's plans to develop and commercialize TN-401 and its other product candidates; the potential for RIDGE-1 clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; risks associated with the process of discovering, developing and commercializing therapies that are safe and effective for use as human therapeutics; Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials, and obtain approvals, for any of its product candidates; Tenaya's continuing compliance with applicable legal and regulatory requirements; Tenaya's ability to raise any additional funding it will need to continue to pursue the clinical development of TN-401 and its other product candidates, as well as Tenaya's general business plans; Tenaya's reliance on third parties; Tenaya's manufacturing, commercialization and marketing capabilities and strategy; the loss of key scientific or management personnel; competition in the industry in which Tenaya operates; Tenaya's ability to obtain and maintain intellectual property protection for its product candidates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in Tenaya's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, and future documents that Tenaya files from time to time with the Securities and Exchange Commission. These forward-looking statements are made as of the date of this press release, and Tenaya assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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