# Tenaya Therapeutics Launches Operations of New Genetic Medicines Manufacturing Center to Support the Development of Potentially First-In-Class Cardiovascular Therapeutics

June 16, 2022

*Facility to Provide Clinical Supply of Lead Gene Therapy Programs TN-201 and TN-401 for Planned First-in-Human Studies*

*94,000 sq. ft. Modular Facility has Initial Production Capacity at the 1000L Scale*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 16, 2022-- Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a biotechnology company with a mission to discover, develop and deliver curative therapies that address the underlying causes of heart disease, today announced that it has completed the build-out and operational launch of its Genetic Medicines Manufacturing Center in Union City, California. Tenaya is advancing a pipeline of therapeutic candidates, including several adeno-associated virus (AAV) gene therapies, for the potential treatment of both rare and prevalent forms of heart disease.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220616005336/en/


Tenaya's Genetic Medicines Manufacturing Center located in Union City, CA (Photo: Business Wire)

"Tenaya made an early, strategic commitment to internalize several core capabilities to optimize the safety, efficacy, and supply of our product candidates on behalf of patients. With today's announcement we have made a big leap forward on that commitment by establishing end-to-end in-house manufacturing capabilities for our pipeline of AAV-based gene therapies," said Faraz Ali, Chief Executive Officer of Tenaya. "The operational launch of Tenaya's Genetic Medicines Manufacturing Center represents an important milestone as we prepare to advance our robust pipeline of potentially first-in-class cardiovascular therapies into initial clinical studies."

Tenaya's Genetic Medicines Manufacturing Center is designed to meet regulatory requirements for production of AAV gene therapies from discovery through commercialization under Current Good Manufacturing Practice (cGMP) standards. Initial production efforts will support first-in-human studies of Tenaya's lead gene therapy, TN-201. TN-201 is being developed for the treatment of genetic hypertrophic cardiomyopathy (HCM) due to *MYBPC3* gene mutations. Tenaya plans to submit an Investigational New Drug (IND) application for TN-201 to the U.S. Food and Drug Administration (FDA) in the second half of this year. The facility will also support cGMP production for TN-401, Tenaya's gene therapy program being developed for the treatment of genetic arrhythmogenic right ventricular cardiomyopathy (ARVC) due to *PKP2* gene mutations, for which the company plans to submit an IND to the FDA in 2023.

"The investment in our own world-class manufacturing facility provides Tenaya with greater control over product attributes, quality, production timelines and costs, which we believe will ultimately translate into better treatments for patients," said Kee-Hong Kim, Ph.D., Chief Technology Officer of Tenaya Therapeutics. "Tenaya's Genetic Medicines Manufacturing Center complements our established internal genetic engineering and drug discovery capabilities and is designed to meet our near- and long-term needs such that we can readily scale and expand as our pipeline matures and evolves."

Tenaya completed customization of approximately half of the 94,000 square foot facility to incorporate manufacturing suites and labs, office space and storage. Utilizing a modular design, the state-of-the-art facility is now fully operational with initial capacity to produce AAV-based gene therapies at the 1000L scale, utilizing Tenaya's proprietary baculovirus-based production platform and suspension Sf9 cell culture system. The excess space and modular design of the Genetic Medicines Manufacturing Center is intended to provide Tenaya with considerable flexibility to expand manufacturing capacity by increasing both the number and the scale of bioreactors to meet future clinical and commercial production needs.

The Union City location, approximately 30 miles from Tenaya's South San Francisco headquarters, is expected to enable the seamless transition of Tenaya's science from early research through commercial manufacturing. The selection of this location is intended to foster a culture of close collaboration across teams at all stages of developing and testing novel AAV capsids, de-risk the translation from research to process development and create opportunities for improvements in production processes. The Genetic Medicines Manufacturing Center is staffed by a growing in-house

team with expertise in all aspects of gene therapy manufacture, including process development, analytical development, quality assurance and quality control.

**About Tenaya Therapeutics**

Tenaya Therapeutics is a biotechnology company committed to a bold mission: to discover, develop and deliver curative therapies that address the underlying drivers of heart disease. Founded by leading cardiovascular scientists from Gladstone Institutes and the University of Texas Southwestern Medical Center, Tenaya is developing therapies for rare genetic cardiovascular disorders, as well as for more prevalent heart conditions, through three distinct but interrelated product platforms: Gene Therapy, Cellular Regeneration and Precision Medicine. 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 "potential," "will," "plans," "believe," "expected," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the therapeutic potential of Tenaya's pipeline of therapeutic candidates; Tenaya's plan to use the cGMP manufacturing facility for the production of TN-201 and TN-401; Tenaya's belief that it's cGMP manufacturing facility will enable seamless transition from early research through commercial manufacturing and translate into better treatments for patients; the expected timing for submission of IND applications for TN-201 and TN-401; and statements by Tenaya's chief executive officer and chief technology 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: risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as an early stage company; Tenaya's ability to successfully manufacture product candidates in a timely and sufficient manner that is compliant with regulatory requirements; Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials, and obtain approvals, for any of its product candidates; the timing, progress and results of preclinical studies for TN-201, TN-401 and Tenaya's other programs; Tenaya's ability to raise any additional funding it will need to continue to pursue its business and product development plans; negative impacts of the COVID-19 pandemic on Tenaya's manufacturing and operations, including preclinical studies and planned clinical trials; the timing, scope and likelihood of regulatory filings and approvals; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; 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 reliance on third parties; 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 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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