



## Tenaya Highlights Growing Capabilities in AAV Manufacturing, Capsid Engineering and Expansion into Gene Editing with Six Abstracts Accepted for Presentation at the ASGCT 26th Annual Meeting

May 3, 2023

### Continued Innovation Across Platforms Facilitates Current Pipeline Advancements and Increases Opportunities for Future Pipeline Candidates

SOUTH SAN FRANCISCO, Calif., May 03, 2023 (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, announced that several abstracts have been accepted for presentation at the American Society of Gene and Cell Therapy (ASGCT) 26<sup>th</sup> Annual Meeting detailing the company's expanded capabilities for manufacturing and discovering genetic medicines for heart disease.

"Tenaya was founded with a singular focus on developing novel medicines for rare and prevalent forms of heart disease. To be a leader in this space requires a sustained commitment to differentiated platform capabilities that enable us to optimize the product profile for our therapeutic candidates and to address new conditions where there is high unmet need," said Faraz Ali, Chief Executive Officer of Tenaya. "The presentations at this year's ASGCT highlight innovations in manufacturing, capsid engineering and gene editing, that support the advancement of our current pipeline and create new opportunities for future pipeline candidates. We look forward to sharing work on additional innovative enabling technologies and genetic medicine programs at future meetings."

The ASGCT 26<sup>th</sup> Annual Meeting is being held in Los Angeles, California May 16-20, 2023. Details of the company's upcoming presentations at ASGCT are available below:

#### Manufacturing and Process Development

TN-201 is an adeno-associated virus (AAV) gene therapy being advanced into the clinic for the treatment of *MYBPC3*-associated hypertrophic cardiomyopathy (HCM). Clinical supply of TN-201 was manufactured under current Good Manufacturing Practice regulations at Tenaya's Genetic Medicines Manufacturing Center using the company's proprietary Sf9 recombinant baculovirus (Sf9/rBV) production process at the 1000L scale. At ASGCT, Tenaya researchers will present data detailing the scale up, formulation and purification techniques deployed in the successful initial manufacture of TN-201.

In addition to the Sf9/rBV manufacturing platform, Tenaya has also internalized the HEK293 manufacturing platform up to the 200L scale. Tenaya researchers will present data on a novel small molecule additive that increases the productivity of HEK293-based AAV manufacturing processes, which may have implications for improved scalability, yields and costs.

#### **Wednesday Poster Session, May 17, 2023, at 12 pm PT**

Development of Cost-Effective and Scalable Recombinant Baculovirus Production Process for the Manufacturing of AAV (Abstract #409)

**Lead author:** Charles Feathers, Process Development Manager, Tenaya Therapeutics

Development of a Comprehensive and Risk-Based Viral Safety Assurance Strategy for the Manufacturing of AAV Gene Therapy (Abstract #408)

**Lead author:** Samantha Jones, Senior Manager, Process Development, Tenaya Therapeutics

Titer Boosting of HEK293-based AAV Manufacturing Process using Proprietary Small Molecule Additive and Successful Scale up to 200L (Abstract #407)

**Lead author:** Jackson Leong, Associate Scientist, Process Development, Tenaya Therapeutics

#### **Thursday Poster Session, May 18, 2023, 12 pm PT**

Development of Rational Formulation for the Delivery of AAV Viral Vector for Treatment of Heart Disease (Abstract #1010)

**Lead author:** Joseph Woods, Process Development Associate, Tenaya Therapeutics

#### Capsid Engineering

AAV9 is the current capsid of choice for cardiovascular indications and the capsid being used in Tenaya's TN-201 and TN-401 gene therapy product candidates. Through rigorous testing across multiple species, Tenaya has identified several novel AAV capsids with greater transduction efficiency for the heart and/or de-targeting of the liver compared to AAV9, that may be used in second generation approaches and for new product candidates. At ASGCT, Tenaya scientists will present new data from non-human primate studies for previously identified novel capsids.

#### **Wednesday Poster Session, May 17, 2023, at 12 pm PT**

Engineering Novel AAV Capsids for Cardiac Gene Delivery (Abstract #463)

**Lead author:** Ze Cheng, Ph.D., Senior Scientist, Tenaya Therapeutics

#### Gene Editing

Phospholamban (PLN) plays a key role in the functioning of the heart, and carriers of the R14del pathogenic variant of the *PLN* gene have a high risk of developing a form of dilated cardiomyopathy that may result in severe arrhythmia, heart failure, and sudden cardiac death. At ASGCT, Tenaya scientists will show data for the first time in which genetic editing using a single AAV vector restores heart function and survival in a severe murine model of PLN cardiomyopathy caused by the R14del mutation. This foundational research will inform future drug development efforts for PLN

cardiomyopathies, as well as for additional cardiomyopathies in which gene editing may be an advantageous approach to correcting specific pathogenetic drivers underlying disease.

**Thursday Poster Session, May 18, 2023, at 12 pm PT**

Gene Editing of R14del Mutation in PLN Rescues PLN-R14del-Associated Cardiomyopathy (Abstract #1113)

**Lead author:** Huanyu Zhou, Ph.D., Senior Scientist, Tenaya Therapeutics

To view full event programming, please visit the ASGCT 26<sup>th</sup> Annual Meeting [website](#). Following the conference, Tenaya's presentations will be available in the "Our Science" section of the company's [website](#).

**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. Leveraging its integrated and interrelated Gene Therapy, Cellular Regeneration and Precision Medicine platforms and proprietary core capabilities, the company is advancing a pipeline of novel therapies with diverse treatment modalities for rare genetic cardiovascular disorders and more prevalent heart conditions. Tenaya's most advanced candidates include 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 small molecule HDAC6 inhibitor being initially developed for heart failure with preserved ejection fraction (HFpEF). Tenaya also has multiple early-stage programs progressing through preclinical development. For more information, visit [www.tenayatherapeutics.com](http://www.tenayatherapeutics.com).

**Forward-looking Statement**

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 "look forward," "may," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding Tenaya's pipeline development plans; future planned presentations; the potential implications for Tenaya's novel small molecule additive on the productivity of HEK293-based AAV manufacturing processes; the therapeutic of novel capsids identified by Tenaya and the potential to use them for new product candidates; 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: 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; the availability of data at the referenced times; the timing, scope and likelihood of regulatory filings and approvals for Tenaya's product candidates; Tenaya's ability to initiate and complete clinical trials for its product candidates; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; the level of costs associated with Tenaya's research, development, manufacturing and other activities and the company's ability to raise any additional funding it will need to continue to pursue its business and product development plans; Tenaya's ability to successfully operate a manufacturing facility for clinical or commercial supply; Tenaya's 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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