Tenaya Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

November 8, 2023

Commenced Patient Dosing in MyPeak-1™ Phase 1b Trial of TN-201 in MYBPC3-Associated Hypertrophic Cardiomyopathy

Presented Positive Phase 1 Data for TN-301 for the Potential Treatment of Heart Failure with Preserved Ejection Fraction at HFSA 2023

TN-401 for PKP2-Associated ARVC Received FDA Clearance to Begin First-in-Human Clinical Testing and Fast Track Designation

SOUTH SAN FRANCISCO, Calif., Nov. 08, 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, today reported financial results and provided a corporate update for the third quarter ended September 30, 2023.

“The successful execution across all of our program milestones slated for 2023, including two gene therapy INDs cleared and the dosing of the first patient in our TN-201 clinical trial, represents the strong commitment and capabilities of our team,” said Faraz Ali, Chief Executive Officer of Tenaya. “We have momentum as we head into 2024, with three clinical-stage programs for the treatment of rare and prevalent heart conditions and unmatched capabilities focused on the discovery of precision heart disease medications.”

Business and Program Updates

TN-201 – Gene Therapy for MYBPC3-Associated Hypertrophic Cardiomyopathy (HCM)

- In October 2023, Tenaya dosed the first patient in the MyPeak-1 Phase 1b clinical trial of TN-201 for the treatment of myosin binding protein C3 (*MYBPC3*)-associated hypertrophic cardiomyopathy (HCM). MyPeak-1 (NCT05836259) is a multi-center, open-label, dose-escalation trial designed to assess safety, tolerability and clinical efficacy of a one-time intravenous infusion of TN-201.
    - Tenaya anticipates sharing initial data from the MyPeak-1 trial in 2024.
- In October 2023, Tenaya shared interim results from its ongoing seroprevalence study indicating that patients with *MYBPC3*-associated HCM have low levels of preexisting neutralizing antibodies to adeno-associated virus serotype 9 (AAV9) and the majority of patients could be eligible for TN-201 treatment in clinical trials.
    - The seroprevalence study is being conducted across 10 clinic sites. As of the data cut off in August 2023, 76 patients with *MYBPC3*-associated HCM were enrolled. These data were presented at the HCM Society (HCMS) Scientific Sessions.

TN-401 – Gene Therapy for PKP2-Associated Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)

- In October 2023, the U.S. Food and Drug Administration (FDA) notified Tenaya that clinical testing of TN-401 may proceed based on review of the company’s Investigational New Drug (IND) application.
    - Tenaya is advancing TN-401 into the clinic for the treatment of plakophilin-2 (*PKP2*)-associated arrhythmogenic right ventricular cardiomyopathy (ARVC), a dangerous condition estimated to effect 70,000 people in the U.S.
    - The company plans to initiate the RIDGE-1™ Phase 1b clinical trial of TN-401 at leading U.S. centers for ARVC treatment and is currently conducting a non-interventional seroprevalence and natural history study among *PKP2*-associated ARV patients.
    - cGMP grade clinical trial material for TN-401 was produced at the 1000L scale at Tenaya’s Genetic Medicine Manufacturing Center.
- In November, TN-401 received Fast Track Designation from the FDA. The FDA Fast Track program is designed to facilitate the development and expedite the review of drug candidates intended to treat serious conditions and for which nonclinical data demonstrates the potential to address unmet medical need.
- In September 2023, Tenaya received Orphan Medicinal Product designation from the European Medicines Agency (EMA) for TN-401 for the potential treatment of ARVC caused by *PKP2* genetic mutations. TN-401 has also Orphan Drug Designation from the U.S. FDA.

TN-301 – Small Molecule HDAC6 Inhibitor for Heart Failure with Preserved Ejection Fraction (HFpEF)

- In October 2023, Tenaya shared positive Phase 1 data for TN-301 at the 2023 Heart Failure Society of America (HFSA) Annual Scientific Meeting.
    - The Phase 1 trial enrolled 72 participants in two stages, single ascending doses (SAD) and multiple ascending doses (MAD).
    - TN-301 was generally well tolerated across the broad range of doses studied. Pharmacokinetic (PK) results showed overall dose proportionality in the SAD and MAD stages of the study with a half-life supportive of once-daily dosing.
    - Robust HDAC6 inhibition was observed and increasing doses and exposures with TN-301 correlated with increased pharmacodynamic (PD) effects. Plasma exposure and target engagement observed in this healthy participant study met or exceeded those required for maximal efficacy in preclinical studies.
- At HFSA Tenaya also presented new preclinical results demonstrating additive benefit of combining TYA-018 (an HDAC6 inhibitor structurally and functionally similar to TN-301) with empagliflozin (a sodium-glucose cotransporter-2 inhibitor), which is approved for the treatment of HFpEF. This builds on the growing body of evidence supporting the multi-modal mechanism of action that is orthogonal from SGLT2 inhibitors.

Research

- In October 2023, Tenaya published preclinical research in the American Heart Association's (AHA) journal, *Circulation*, detailing its initial success in cardiac cellular regeneration utilizing a single AAV vector to deliver specific combinations of genes to reprogram cells in the heart following ischemic injury.

Third Quarter 2023 Financial Highlights

- **Cash Position and guidance:** As of September 30, 2023, cash, cash equivalents and investments in marketable securities were $128.1 million. Tenaya expects current cash, cash equivalents and investments in marketable securities (current and noncurrent) will be sufficient to fund the company into the first half of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2023, were $23.1 million. Non-cash stock-based compensation included in R&D expense was $1.9 million for the quarter ended September 30, 2023.
- **General & Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2023, were $7.8 million. Non-cash stock-based compensation included in G&A expense was $2.2 million for the quarter ended September 30, 2023.
- **Net Loss:** Net loss for the quarter ended September 30, 2023, was $29.1 million, or $0.39 per share.

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.

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," "anticipates," "plans," "expects," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, the clinical, therapeutic and commercial potential of, and expectations regarding, Tenaya's product candidates; Tenaya's plans and expectations regarding its clinical development efforts and activities, including the planned timing of sharing initial data from the Phase 1b clinical trial of TN-201 and planned initiation of a Phase 1b clinical trial of TN-401; the sufficiency of Tenaya's cash resources to fund the company into the first half 2025; and statements made 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; 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; the availability of data at the referenced times; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; Tenaya's ability to raise any additional funding it will need to continue to pursue its business and product development 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 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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TENAYA THERAPEUTICS, INC.

Condensed Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 23,091	$ 23,758	$ 75,173	$ 68,789
General and administrative	7,829	7,540	24,574	22,282
Total operating expenses	30,920	31,298	99,747	91,071
Loss from operations	(30,920)	(31,298)	(99,747)	(91,071)
Other income, net:				
Interest income	1,776	596	5,586	917
Other income, net	1	6	12	5
Total other income, net	1,777	602	5,598	922
Net loss before income tax expense	(29,143)	(30,696)	(94,149)	(90,149)
Income tax expense	—	—	—	—
Net loss	$ (29,143)	$ (30,696)	$ (94,149)	$ (90,149)
Net loss per share, basic and diluted	$ (0.39)	$ (0.74)	$ (1.28)	$ (2.18)
Weighted-average shares used in computing net loss per share, basic and diluted	73,924,937	41,358,296	73,579,200	41,309,812

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 128,120	$ 204,230
Total assets	$ 193,397	$ 278,945
Total liabilities	$ 28,513	$ 35,569
Total liabilities and stockholders' equity	$ 193,397	$ 278,945