Tenaya Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 8, 2023

TN-201 IND Cleared in January; Plan to Begin Phase 1b Dosing in MYBPC3-associated HCM Patients in Third Quarter 2023

Dosing Commenced in Multiple-Ascending Dose Stage of First-In-Human Clinical Trial of TN-301; Data Anticipated in Second Half 2023

2022 Year End Cash and Investments of $204 Million; Runway to Fund Operations into First Half 2025

SOUTH SAN FRANCISCO, Calif., March 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 for the fourth quarter and full year ended December 31, 2022, and provided a corporate update.

“Tenaya enters 2023 well capitalized and with meaningful milestones ahead,” said Faraz Ali, Chief Executive Officer of Tenaya. “This year, we look forward to beginning clinical testing of our lead gene therapy candidate, TN-201, sharing data from our first-in-human clinical trial of TN-301, and submitting an IND for our TN-401 gene therapy candidate, as well as presenting additional data detailing insights on current pipeline candidates and emerging platform innovations.”

Business and Program Updates

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

- In January 2023, Tenaya received notification from the U.S. Food and Drug Administration (FDA) that clinical testing of TN-201 may proceed based on the agency’s review of the company’s Investigational New Drug (IND) application. TN-201 is designed to deliver a fully functional *MYBPC3* gene to restore normal levels of MyBP-C protein and thereby potentially halt disease progression and reverse the course of genetic HCM after a single dose.
- Tenaya plans to commence a Phase 1b multi-center, open-label, dose-escalation study to assess the safety, tolerability and pharmacodynamics of a one-time intravenous infusion of TN-201 in symptomatic adults with *MYBPC3*-associated HCM in the third quarter of 2023. Initial data from the Phase 1b trial are anticipated in 2024.

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

- Tenaya commenced dosing of healthy participants in the multiple-ascending dose (MAD) stage of its ongoing Phase 1 trial evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of escalating oral doses of TN-301, a highly selective small molecule inhibitor of HDAC6 being developed for the potential treatment of HFpEF.
    - TN-301 was generally well tolerated during the single ascending (SAD) stage of Tenaya’s randomized, double-blind, placebo-controlled Phase 1 trial.
    - Initial target engagement, measured by the biomarker of tubulin acetylation, was achieved at dose levels thought to be in therapeutic ranges based on preclinical experiments.
- Tenaya expects to report data from both the SAD and MAD stages of the Phase 1 clinical trial in the second half of 2023.

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

- Tenaya plans to submit an IND application for TN-401 to the FDA in the second half of 2023. IND-enabling studies and manufacturing of clinical supply are currently underway. TN-401 is designed to deliver a fully functional *PKP2* gene to reverse disease and prevent arrhythmia after a single dose.

Financing:

- In November 2022, Tenaya completed a follow-on public offering of approximately 25.4 million shares of its common stock and, to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of approximately 6.2 million shares at a public offering price of $2.60 per share and $2.599 per pre-funded warrant. The net proceeds to Tenaya were $76.9 million after discounts, commissions, and other offering expenses.

Fourth Quarter and Full Year 2022 Financial Highlights

Cash Position: As of December 31, 2022, cash, cash equivalents and investments in marketable securities (current and noncurrent) were $204.2 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 were $25.7 million for the fourth quarter and $94.5 million for the full year ended December 31, 2022. Non-cash stock-based compensation included in R&D expense was $1.1 million for the fourth quarter and $4.9 million for the full year ended December 31, 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses were $8.8 million for the fourth quarter and $31.1 million for the full year ended December 31, 2022. Non-cash stock-based compensation included in G&A expense was $2.1 million for the fourth quarter and $6.6 million for the full year ended December 31, 2022.
- **Net Loss:** Net loss was $33.5 million, or $0.61 loss per share for the fourth quarter ended December 31, 2022. For the full year 2022, net loss was $123.7 million, or $2.76 per share. The number of Tenaya's common stock outstanding as of December 31, 2022, was 66.9 million shares.

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 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," "plans," "anticipated," "expects," "will," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding 2023 key milestones, including the initiation of clinical testing of TN-201, data from the first-in-human clinical trial of TN-301, submission of the TN-401 IND and the presentation of data from pipeline candidates and platform innovations; expected timing for, commencement of dosing in the Phase 1b clinical trial evaluating TN-201 and availability of initial data from the trial, data from the SAD and MAD stages of the Phase 1 clinical trial evaluating TN-301 and the submission of the TN-401 IND; the potential of, and expectations regarding, Tenaya's product candidates; the sufficiency of Tenaya's cash resources to fund the company into the first half 2025; 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: Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials for its product candidates; the timing, scope and likelihood of regulatory filings and approvals; the availability of data at the referenced times; 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 raise any additional funding it will need to continue to pursue its business and product development plans; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; 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; negative impacts of the COVID-19 pandemic on Tenaya's operations, including preclinical studies, planned clinical trials and manufacturing activities; 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 December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 25,748	$ 20,953	$ 94,537	$ 54,393
General and administrative	8,802	5,211	31,084	18,413
Total operating expenses	34,550	26,164	125,621	72,806

Loss from operations	(34,550)	(26,164)	(125,621)	(72,806)
Other income (expense), net:				
Interest income	1,037	67	1,954	108
Other income (expense), net	(3)	(54)	2	(23)
Total other income (expense), net	1,034	13	1,956	85
Net loss before income tax expense	(33,516)	(26,151)	(123,665)	(72,721)
Income tax expense	—	—	—	—
Net loss	(33,516)	(26,151)	(123,665)	(72,721)
Net loss per share, basic and diluted	$ (0.61)	$ (0.63)	$ (2.76)	$ (4.10)
Weighted-average shares used in computing net loss per share, basic and diluted	55,250,372	41,253,720	44,823,597	17,734,166

TENAYA THERAPEUTICS, INC.

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	December 31,	
	2022	**2021**
Cash, cash equivalents and marketable securities	$ 204,230	$ 251,300
Total assets	$ 278,945	$ 314,189
Total liabilities	$ 35,569	$ 35,663
Total liabilities and stockholders' equity	$ 278,945	$ 314,189