Tenaya Therapeutics Provides 2022 Business Updates

January 10, 2022

- *Company announces development candidate selection of its second gene therapy program, TN-401, targeting the leading genetic cause of arrhythmogenic right ventricular cardiomyopathy (gARVC)*
- *IND applications for TN-201 and TN-301 (previously named TYA-11631) expected to be submitted in the second half of 2022*
- *Appoints Jennifer Drimmer, J.D., as General Counsel*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 10, 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 provided a 2022 business update including the selection of TN-401 as the development candidate for the treatment of Genetic Arrhythmogenic Right Ventricular Cardiomyopathy (gARVC) due to *PKP2* gene mutation. In addition, Tenaya appointed Jennifer Drimmer, J.D., as its General Counsel.

“After an exciting year in 2021, Tenaya is off to a strong start in 2022 with the selection of TN-401 as a development candidate that provides new hope to patients and families fighting gARVC,” said Faraz Ali, Chief Executive Officer of Tenaya. “With three therapeutic candidates now advancing toward the clinic, we look forward to another year of important milestones and operational and scientific progress. We also continue to strengthen the leadership team with the appointment of Jennifer who adds highly relevant experience, depth, and diversity. We have never been better positioned to deliver on our mission to fundamentally change the paradigm of treatment for both rare and prevalent forms of heart disease.”

Business and Program Updates

- **TN-401 - *PKP2* Gene Therapy Program for Genetic Arrhythmogenic Right Ventricular Cardiomyopathy (gARVC):**
  - Tenaya has nominated TN-401 as a clinical drug candidate to treat patients carrying *PKP2* gene mutations. Mutations of the *PKP2* gene are the leading genetic cause of ARVC and can cause severe disease including significant arrhythmia and sudden cardiac death in adults and children. These mutations are estimated to affect more than 70,000 patients in the US alone. Based on publicly available information to date, we believe there are no approved disease-specific therapies.
  - Tenaya expects to present new preclinical data supporting the TN-401 program including dose-dependent efficacy, survival durability, and mechanistic insights at a scientific conference in 2022.
  - Tenaya has successfully scaled up production of TN-401 to 200L and is initiating IND enabling studies. Tenaya will also support establishment of a global natural history study in 2022 and expects to submit an IND in 2023.
- **TN-201 – *MYBPC3* Gene Therapy Program for Genetic Hypertrophic Cardiomyopathy (gHCM):**
  - Tenaya has previously announced initiation of IND-enabling activities and expects to submit an IND to the FDA in the second half of 2022.
  - The safety and efficacy of TN-201 will initially be explored in symptomatic adult patients with *MYBPC3* mutations and the non-obstructive form of HCM (nHCM). Approximately 70% of patients with truncating *MYBPC3* mutations have the nHCM form of the disease where surgical myectomy is not an option and the unmet need is high.
  - Tenaya continues site activation and patient enrollment in the MyClimb global natural history study to support and potentially expedite the future evaluation of TN-201 in pediatric patients during clinical development after early safety has been established in adults.
  - TN-201 has been granted orphan drug designation by the FDA.
- **TN-301 – HDAC6 Inhibitor (Small Molecule for Heart Failure with Preserved Ejection Fraction):**
  - Tenaya has continued to generate strong preclinical data supporting the multi-modal mechanism of action of TN-301 in multiple disease models and expects to present these at a scientific conference in 2022.
  - Tenaya has previously announced initiation of IND-enabling activities and a cGMP manufacturing campaign and expects to submit an IND to the FDA in the second half of 2022.
  - The safety, tolerability, pharmacokinetics, and pharmacodynamics of TN-301 will initially be assessed in healthy volunteers, as well as possibly in pre-diabetic participants to assess target engagement and proof of activity.
- **Manufacturing:**

- Tenaya expects its state-of-the-art, modular cGMP manufacturing facility in Union City, California will become operational in the first half of 2022, and will support the production of drug product at multiple scales for clinical studies for all AAV-based programs, including TN-201 and TN-401.

- **Leadership Team:**
  - Tenaya continues to strengthen its leadership team with the appointment of Jennifer Drimmer, J.D., as its General Counsel. Jennifer has more than 17 years of experience including public company expertise and executive leadership in corporate governance, contracting, mergers and acquisitions, and legal operations. She previously served as Senior Vice President of Corporate Legal Affairs and Secretary at Exelixis, Inc. (NASDAQ: EXEL) responsible for leading the corporate governance and public company reporting functions. Ms. Drimmer received her B.A. from the University of California, San Diego, and her J.D. from the University of California, Davis School of Law.

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 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 "expects" and "will," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the expected timing of IND applications for TN-201, TN-301 and TN-401, statements regarding the potential of and expectations regarding Tenaya's product candidates and programs, including TN-201, TN-301 and TN-401, statements regarding the cGMP manufacturing facility, expectations with respect to various scientific conferences, the sufficiency of projected cash flows, 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; 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-301, 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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