Cadrenal Therapeutics Provides Fiscal Year 2022 Corporate Update

PONTE VEDRA, Fla., March 30, 2023 /PRNewswire/ — **Cadrenal Therapeutics, Inc.**, (Nasdaq: CVKD) a biopharmaceutical company focused on developing tecarfarin, a late-stage novel cardiorenal therapy with orphan drug and Fast Track designations, today provided a corporate update in connection with the filing of its Annual Report on Form 10-K for the year ended December 31, 2022.

Recent Highlights

- U.S. Food and Drug Administration ("FDA") granted Fast Track designation for tecarfarin for the prevention of systemic thromboembolism of cardiac origin in patients with end-stage renal disease and atrial fibrillation.
- Formed Scientific Advisory Board (SAB) in support of the development of tecarfarin for the prevention of systemic thromboembolism.
- Appointed Douglas Losordo as Chief Medical Officer, and Matthew Szot as Chief Financial Officer.
- Rang the Nasdaq closing bell on February 8, 2023.
- Completed an initial public offering ("IPO") raising gross proceeds of $7.0 million with the listing of its common shares on the Nasdaq Capital Market.

"Over the past year, we have taken significant steps to advance the development of tecarfarin, a novel therapy designed for the prevention of blood clots of cardiac origin in patients with end-stage renal disease and atrial fibrillation," commented Quang Pham, CEO of Cadrenal Therapeutics. "Following our acquisition of the rights to tecarfarin in April 2022, we moved quickly to assemble a world-class group of anticoagulant, medical and scientific experts to provide strategic guidance to Cadrenal, and brought on key management team members to advance our mission. Earlier this year, we successfully received Fast Track designation from the U.S. FDA for tecarfarin and completed our initial public offering. We are currently planning a Phase 3 clinical trial for tecarfarin based on feedback previously received by the U.S. FDA. We look forward to working closely with the FDA to evaluate this therapy as a potential new treatment option for the severely underserved patient population that has end-stage renal disease and atrial fibrillation."

Tecarfarin

Tecarfarin, which has been granted orphan drug and Fast Track designations by the U.S. FDA, for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with End-Stage Renal Disease (ESRD) and Atrial Fibrillation (AFib), is a Vitamin K antagonist oral anticoagulant designed to target a different pathway than the most commonly prescribed drugs used in the treatment of thrombosis and AFib. Tecarfarin has been evaluated in 11 human clinical trials and more than 1,000 individuals. In Phase 1, Phase 2 and Phase 2/3 clinical trials, tecarfarin has generally been well-tolerated in both healthy adult subjects and patients with chronic kidney disease. Cadrenal secured the rights to tecarfarin on April 1, 2022 via an asset purchase agreement. Approximately $90 million has been invested to date in clinical and regulatory work by previous owners of tecarfarin.

Cadrenal believes its Phase 3 will be the remaining pivotal trial. The Phase 3 trial, called Anti-Coagulation with Tecarfarin on Outcomes in Renal disease and AFib (ACTOR-AF) is designed as a Phase 3, 492-patient, randomized, double-blind, placebo-controlled outcomes study of tecarfarin vs. placebo in subjects with ESRD and AFib not currently treated with chronic oral anticoagulation.

Dr. Douglas Losordo, Chief Medical Officer of Cadrenal, commented, “It is a unique opportunity to have a late-stage cardiovascular drug with only one expected remaining pivotal trial remaining until NDA submission. We look forward to advancing the Phase 3 ACTOR-AF trial with the goal of providing a stroke prevention therapy to a high-risk population with no current proven treatment options.”

Market Opportunity

The presence of either chronic kidney disease (CKD) or AFib increases the risk of serious thromboembolic adverse clinical outcomes, such as stroke and death. AFib increases the risk of stroke by 5 times and is the most common arrhythmia. ESRD further doubles the risk of stroke. Antithrombotic therapy is typically recommended to decrease this risk in AFib patients, but there are no therapies for patients that have ESRD with AFib that have been proven to lower the risk of stroke.

Overall, CKD affects almost 40 million American adults, with as many as 90% of Americans who have CKD not knowing they have the disease until it is very advanced. A more dire subset is the more than 800,000 Americans with ESRD, or permanent kidney failure that requires life-long dialysis or a kidney transplant. Nearly 20% of ESRD patients, or 150,000 individuals, also have AFib or an irregular heartbeat, which nearly doubles the anticipated mortality and increases the stroke risk by approximately five-fold in these patients. There is evidence that AFib is an independent risk factor for developing ESRD in CKD patients. Both diseases share common risk factors including hypertension, diabetes, vascular disease, and advancing age. Cardiovascular disease contributes to more than half of all deaths among patients with ESRD.

According to the Annual Data Report published by the United States Renal Data System, total Medicare spending for patients with ESRD reached $51 billion in 2019, accounting for approximately 7% of the Medicare paid claims costs. Based upon a 2019 study, adjusted for inflation, the U.S. market potential for tecarfarin is estimated up to $1 billion annually if approved by the FDA.

Pham continued, “The presence of either chronic kidney disease or AFib increases the risk of serious thromboembolic adverse clinical outcomes, such as stroke and death. Antithrombotic therapy is typically recommended to decrease this risk in AFib patients, but unfortunately there are no approved therapies for patients that have ESRD with AFib. Cadrenal hopes tecarfarin can be the answer for this group of patients which carry a high morbidity rates and exorbitant costs to the American healthcare system due to lack of effective treatment.”

Orphan Drug and Fast Track Designations

The FDA has granted tecarfarin both orphan drug designation (ODD) and Fast Track designation to tecarfarin for the prevention of systemic thromboembolism, more commonly referred to as blood clots, of cardiac origin in patients with ESRD and AFib.

The FDA grants ODD status to drugs that are intended for the treatment, diagnosis, or prevention of rare diseases or conditions, which are defined as a disease or condition that affects fewer than 200,000 people in the U.S. The ODD program provides a drug developer with certain benefits and incentives, including a seven-year period of U.S. marketing exclusivity from the date of marketing authorization, waiver of FDA user fees, and tax credits for clinical research.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of Fast Track is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions.

Scientific Advisory Board

“Cadrenal is fortunate to have engaged thought leaders in the key disciplines involved in our tecarfarin program. We look forward to their guidance as we advance this program to completion,” continued Dr. Losordo.

Please click here to view the Company’s Scientific Advisory Board.

Corporate Slide Presentation

Cadrenal recently posted a corporate slide presentation on its website. To view the presentation, please visit: https://www.cadrenal.com/investors/.

ABOUT CADRENAL THERAPEUTICS, INC.

Cadrenal Therapeutics is focused on developing tecarfarin, a novel cardiorenal therapy with orphan drug and Fast Track designations for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end-stage renal disease, or ESRD, and atrial fibrillation (irregular heartbeat), or AFib. Tecarfarin is a Vitamin K antagonist oral anticoagulant designed to target a different pathway than the most commonly prescribed drugs used in the treatment of thrombosis and AFib. Tecarfarin has been evaluated in eleven (11) human clinical trials and more than 1,000 individuals. In Phase 1, Phase 2 and Phase 2/3 clinical trials, tecarfarin has generally been well-tolerated in both healthy adult subjects and patients with CKD. For more information, please visit: www.cadrenal.com.

Safe Harbor Statement

Any statements contained in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements.” These statements include statements regarding planning a Phase 3 clinical trial for tecarfarin as a potential new treatment option for the severely underserved patient population that has end-stage renal disease and atrial fibrillation, planning a Phase 3 clinical trial for tecarfarin based on feedback previously received by the U.S. FDA, working closely with the FDA to evaluate this therapy as a potential new treatment option for this severely underserved patient population and tecarfarin, tecarfarin having one expected pivotal trial remaining until NDA submission and tecarfarin being the answer for patients with either chronic kidney disease or AFib. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the ability to advance the program to completion, the ability to advance patient care in cardiorenal diseases and the other factors discussed in the “Risk Factors” section of the initial public offering prospectus filed with the SEC and the Company’s future filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof and, except as required by federal securities laws, Cadrenal Therapeutics specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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