Cadrenal Therapeutics Provides First Quarter 2023 Corporate Update

PONTE VEDRA, Fla., May 10, 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 today's filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

Recent Highlights

- In January 2023, 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.
- In January 2023, successfully completed its initial public offering on Nasdaq, raising $7.0 million in gross proceeds.
- Formed Scientific Advisory Board (SAB) in support of the development of tecarfarin for the prevention of systemic thromboembolism.
- Rang the Nasdaq closing bell on February 8, 2023.
- Q1 2023 operating expenses (excluding non-cash items) totaled $913,653.
- As of March 31, 2023, cash balances were $4.0 million. The Company believes it has sufficient capital to fund operations through Q2 2024.

"The first quarter of 2023 was one of tremendous progress for Cadrenal following the receipt of Fast Track designation for tecarfarin, and the completion of our initial public offering," commented Quang Pham, CEO of Cadrenal Therapeutics. "We are following the FDA's guidance, including the granting of an orphan drug designation, as well as that of industry-leading cardiologists and nephrologists, to pursue approval for tecarfarin in patients with end-stage renal disease and AFib to meet the widely acknowledged lack of effective treatment options for this patient population. We believe the successful completion of our planned Phase 3 trial will be the final step before submitting our New Drug Application for approval review. We look forward to working closely with the FDA to evaluate this therapy as a potential new treatment option."

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 planned 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.

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 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.

Based upon a 2019 study, adjusted for inflation, the U.S. market potential for tecarfarin is estimated at up to $1 billion annually if approved by the FDA.

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 seven years 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.

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 pursuing approval for tecarfarin in patients with end-stage renal disease and AFib to meet the widely acknowledged lack of effective treatment options for this patient population, the successful completion of the Company’s planned Phase 3 trial being the final step before submitting its New Drug Application for approval review, working closely with the FDA to evaluate this therapy as a potential new treatment option and the U.S. market potential for tecarfarin being up to $1 billion annually if approved by the FDA. 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 Company’s ability to obtain regulatory approval for the commercialization of tecarfarin or to comply with ongoing regulatory requirements, the Company’s ability to

complete its planned Phase 3 trial on time and achieve desired results and benefits as expected, and the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and the Company's subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K.. 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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