Cadrenal Therapeutics (Nasdaq: CVKD) Granted FDA Fast Track Designation for Tecarfarin for Prevention of Systemic Thromboembolism of Cardiac Origin in Patients with End-Stage Renal Disease and Atrial Fibrillation

PONTE VEDRA, Fla., Jan. 23, 2023 — **Cadrenal Therapeutics (Nasdaq: CVKD)**, a biopharmaceutical company focused on developing tecarfarin, a clinical-stage novel cardiorenal therapy with orphan drug designation, announced today that the U.S. Food and Drug Administration (FDA) has granted a Fast Track designation to tecarfarin for the prevention of systemic thromboembolism, more commonly referred to as blood clots, of cardiac origin in patients with end-stage renal disease (ESRD) and atrial fibrillation (AFib).

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.

“The Fast Track designation for tecarfarin is an important milestone in the development of this therapy and highlights the importance of finding an effective treatment for the prevention of blood clots of cardiac origin in patients with ESRD and AFib,” said Quang Pham, Chief Executive Officer of Cadrenal. “We look forward to working closely with the FDA to evaluate this therapy as a potential new treatment option for this underserved patient population.”

“Patients with ESRD and AFib have not been well represented in clinical trials evaluating stroke prevention,” commented Dr. Sean Pokorney, an electrophysiologist, Assistant Professor of Medicine at Duke University, and Primary Investigator for the ACTOR-AF Tecarfarin versus placebo Phase 3 Trial. “The development of tecarfarin is an exciting opportunity to collect randomized clinical trial data on stroke prevention in patients with ESRD and AFib, and tecarfarin provides a unique opportunity to optimize stroke prevention in patients with ESRD and AFib.”

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with the FDA to discuss the drug’s development plan and

ensure collection of appropriate data needed to support drug approval.
- More frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers.
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

The FDA had previously granted an Orphan Drug Designation (ODD) for tecarfarin. The FDA grants orphan status to drugs targeting rare diseases or disorders that affect 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 if certain criteria are met, waiver of FDA user fees, and tax credits for clinical research.

ABOUT CADRENAL

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 in 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 (CKD). For more information, please visit: www.cadrenal.com.

Safe Harbor Statement

Statements 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, but are not limited to, statements relating to working closely with the FDA to evaluate tecarfarin as a potential new treatment option for the prevention of systemic thromboembolism and tecarfarin providing a unique opportunity to optimize stroke prevention in patients with ESRD and AFib and the expected benefits of Fast Track designation. 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 commercialize tecarfarin as a new treatment option for the prevention of systemic thromboembolism and other factors discussed in the “Risk Factors” section of Cadrenal Therapeutics’prospectus filed with the SEC. 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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