

# CADRENAL THERAPEUTICS PROVIDES THIRD-QUARTER CORPORATE UPDATE

PONTE VEDRA, Fla., Nov. 7, 2024 /PRNewswire/ — Cadrenal Therapeutics, Inc., (Nasdaq: CVKD) (the “Company” or “Cadrenal”), a late-stage biopharmaceutical company developing tecarfarin, a new vitamin K antagonist (VKA) designed to provide safer and superior anticoagulation for patients with implanted cardiac devices or rare cardiovascular conditions, today provided a corporate update coinciding with the filing of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024.



## Recent Highlights

- In early September, Cadrenal leadership met with the U.S. Food and Drug Administration (FDA) to discuss its tecarfarin Phase 3 clinical trial protocol in left ventricular assist device (LVAD) patients and is continuing these discussions.
- Cadrenal advanced Abbott collaboration discussions regarding Cadrenal’s pivotal clinical trial in patients with the Abbott LVAD HeartMate 3, the only LVAD available in the U.S.
- Also, in October 2024, Cadrenal joined the Corporate Council of the Anticoagulation Forum (AC Forum), the largest professional organization of anticoagulation specialists committed to advancing the quality and safety of chronic anticoagulation care globally. Through participation in the Corporate Council, Cadrenal will collaborate with the AC Forum as it works to educate and engage the organization’s 15,000 healthcare professional members to improve outcomes for patients on anticoagulants.
- Cadrenal and its pharmaceutical contract development and manufacturing organization (CDMO) completed the operational readiness activities necessary to supply active pharmaceutical ingredients and clinical trial materials in accordance with current good manufacturing principles (cGMP).
- On October 24, 2024, Cadrenal announced that it successfully raised approximately \$5.1 million through its at-the-market facility (ATM).
- On November 1, 2024, Cadrenal announced the exercise of warrants generating gross proceeds of approximately \$4.7 million.
- Recent financing transactions totaling \$9.8 million increased its cash balance to

approximately \$11.3 million and strengthened its balance sheet. The net proceeds provide Cadrenal with additional working capital as it advances tecarfarin toward a pivotal Phase 3 trial.

- Q3 2024 operating expenses were \$2.5 million, including \$0.3 million of non-cash expenses.
- Cash used in operating activities totaled \$2.2 million during Q3 2024.
- Cash and cash equivalent balance of \$11.3 million as of November 7, 2024.

“Momentum is building from our achievement of several critical milestones toward beginning a pivotal clinical trial to evaluate tecarfarin’s superiority to warfarin in LVAD patients,” said Quang X. Pham, Founder, Chairman, and Chief Executive Officer of Cadrenal Therapeutics. “These accomplishments span finance, operations, partner relations, and clinical development and enhance our ability to execute our strategic plan going into 2025.

“Efficiently raising nearly \$10 million in recent weeks bolsters funds for operational and clinical development needs. At the same time, we are progressing our dialogue with the FDA and Abbott and moving ahead with our CDMO to manufacture tecarfarin for our Phase 3 trial,” continued Pham.

Tecarfarin is the only anticoagulant in development worldwide for patients with implanted cardiac devices and other rare cardiovascular conditions. The oral and reversible drug has been uniquely designed to overcome many of the challenges patients experience with warfarin and to fill a need unmet by direct oral anticoagulants (DOACs) that are contraindicated or not recommended by leading cardiology associations for these individuals. If approved, tecarfarin may be a safer and more effective chronic anticoagulant for LVAD patients in the U.S.

In addition, tecarfarin may prove valuable for other patients where warfarin is not providing recommended anticoagulation because of genetic warfarin resistance or renal impairment making warfarin metabolism difficult. These include individuals with end-stage renal disease and atrial fibrillation or those with mechanical heart valves and hard-to-control anticoagulation, as determined by International Normalized Ratio (INR) measurements of how long it takes the blood to clot.

## **ABOUT CADRENAL THERAPEUTICS, INC.**

Cadrenal Therapeutics is a late-stage biopharmaceutical company developing tecarfarin, a new vitamin K antagonist (VKA) designed to offer safer, more effective chronic anticoagulation for patients with implanted cardiac devices or rare cardiovascular conditions. Tecarfarin is anticipated to result in fewer adverse events such as strokes, heart attacks, bleeds, and deaths than warfarin, the most commonly used anticoagulant for these patients, despite its prevalent adverse events, drug-to-drug interactions, and frequent dosing changes. Cadrenal is focused on evaluating tecarfarin’s superiority to warfarin in these patients where

DOACs are not recommended in the treatment guidelines of leading cardiology associations. Tecarfarin received an orphan drug designation for advanced heart failure patients with implanted LVADs as well as both orphan drug and fast-track status for end-stage kidney disease patients with atrial fibrillation. Cadrenal is opportunistically planning pivotal clinical trials and pursuing clinical and commercial partnerships to advance tecarfarin. The company's plans also include studying tecarfarin in patients with mechanical heart valves experiencing anticoagulation difficulties. Visit [www.cadrenal.com](http://www.cadrenal.com) to learn more.

## **About Tecarfarin**

Tecarfarin is a Phase 3-ready drug candidate that Cadrenal is developing to overcome many of warfarin's challenges and fill the need for a safer and more effective VKA chronic anticoagulant. Tecarfarin is anticipated to improve outcomes and result in fewer major events for warfarin-dependent patients. Extensive data indicates that the efficacy of tecarfarin, metabolized via a different pathway than warfarin, is not affected by drug-drug interactions and kidney impairment, which are common in these patients. Phase 2/3 clinical trials show that tecarfarin may offer enhanced stability and time in therapeutic range (TTR) that inversely correlate with major events. Tecarfarin is the only new anticoagulant being developed for patients with implanted cardiac devices or rare cardiovascular conditions. Treatment with tecarfarin aims to improve anticoagulation for these underserved patients and their healthcare providers who face difficulties in managing warfarin's wide variability and risk of gastrointestinal bleeds.

## **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 our planned pivotal trial to evaluate tecarfarin's effectiveness for LVAD patients, the success of the Company's collaborative efforts with Abbott, tecarfarin potentially being a safer and more effective chronic anticoagulant for patients with LVADs, tecarfarin filling a need unmet by DOACs that are contraindicated or not recommended, the commencement of trials to evaluate tecarfarin's superiority to warfarin in LVAD patients and potentially bring the Company's better anticoagulation solution to those in need, and tecarfarin proving valuable for other patients where warfarin is not providing recommended anticoagulation because of genetic warfarin resistance or renal impairment making warfarin metabolism difficult. 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 of tecarfarin to improve anticoagulation treatment in

patients, the ability of the Company to advance tecarfarin with patients with left ventricular assist devices (LVADs), the collaborative efforts with Abbott being successful and those with AFib and ESKD, the collaboration with Abbott being successful and the other risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's subsequent filings with the Securities and Exchange Commission, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 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, the Company 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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