# Cadrenal Therapeutics Provides 2024 Year-End Company Update, Reinforcing Clinical Development Plan for Tecarfarin in LVAD and Other Rare Cardiovascular Indications

PONTE VEDRA, Fla. – Cadrenal Therapeutics, Inc. (Nasdaq: CVKD) today recapped its 2024 milestones and highlighted a clear path forward to develop the investigational drug tecarfarin as a superior and safer chronic anticoagulant therapy for warfarin-dependent patients with implanted cardiac devices including left ventricular assist devices (LVAD) or for those with rare cardiovascular conditions.

“This year has marked significant opportunities and advancements for Cadrenal Therapeutics, with a strong focus on clinical indications,” said Quang X. Pham, Chairman and Chief Executive Officer of Cadrenal Therapeutics. “The Company has established a targeted plan to advance the clinical development of tecarfarin and, if approved, to commercialize it as a significant improvement for LVAD patients facing challenges with chronic anticoagulation treatments. We look ahead to 2025 and the initiation of the pivotal Phase 3 clinical trial for tecarfarin in LVAD and developing this much-needed therapeutic solution for advanced heart failure patients with implanted LVADs.”

2024 Year-End Highlights:

- **FDA Engagement and Tecarfarin Development**: Cadrenal Therapeutics held a Type B meeting with the U.S. Food and Drug Administration (FDA) regarding the pivotal Phase 3 clinical trial protocol for tecarfarin in LVAD patients. The Company remains in discussion with the FDA to further refine the trial and expects to provide updates on the anticipated trial in Q1 2025.

- **Strategic Development Collaborations**: Cadrenal Therapeutics continues to explore collaboration with potential development partners to advance tecarfarin’s pivotal clinical trial for patients with LVAD and other rare cardiovascular conditions.

- **Financial Growth and Fundraising Success**: Cadrenal Therapeutics raised approximately $9.8 million in recent financing transactions, including $5.1 million through an at-the-market (ATM) facility and $4.7 million from warrant exercises, boosting its cash balance to $11.3 million as of November 2024.

- **Industry Recognition and Engagement**: In October 2024, Cadrenal Therapeutics joined the Corporate Council of the Anticoagulation Forum (AC Forum). This association will enable the Company to collaborate with anticoagulation therapy thought leaders and 15,000 healthcare professionals to improve anticoagulation outcomes for patients globally. In November 2024, Cadrenal Therapeutics was named Anticoagulation Therapy

Company of the Year by *Pharma Tech Outlook*, an industry publication focused on breakthrough pharmaceutical technologies.

- **Operational Milestones**: The Company and its pharmaceutical Contract Development and Manufacturing Organization (CDMO) completed necessary operational readiness activities to supply clinical trial materials for the upcoming tecarfarin pivotal Phase 3 trial in compliance with current Good Manufacturing Practices (cGMP). Cadrenal Therapeutics has also conducted market research in multiple indications, including LVAD, research that reinforces Cadrenal Therapeutics' commitment to continuing pre-commercial work for tecarfarin.

- **Orphan Drug Designation for Tecarfarin**: In April 2024, Cadrenal Therapeutics received FDA Orphan Drug Designation (ODD) for tecarfarin to prevent thromboembolism in patients with LVADs and other mechanical circulatory support devices, underscoring the investigational drug's potential impact on rare cardiovascular conditions. Tecarfarin also has ODD and Fast Track designation from the FDA for the prevention of systemic thromboembolism of cardiac origin in patients with end-stage kidney disease (ESKD) and atrial fibrillation (AFib).

- **Leadership**: Cadrenal appointed Jeff Cole as Chief Operating Officer to oversee manufacturing, supply chain operations, intellectual property, and commercialization strategies.

- **Scientific Advocacy and Clinical Evidence**: The clinical need for tecarfarin was highlighted at the November 2024 European Association for Cardio-Thoracic Surgery (EACTS) Mechanical Circulatory Support Summit in an address by Mandeep R. Mehra, MD, The William Harvey Distinguished Chair in Advanced Cardiovascular Medicine and Professor, Harvard Medical School. Dr. Mehra presented compelling data on the limitations of warfarin for LVAD patients and the potential of tecarfarin, if approved, to provide a safer alternative to these patients.

**About Cadrenal Therapeutics**

Cadrenal Therapeutics, Inc. is a biopharmaceutical company in advanced clinical development focused on developing tecarfarin, a novel oral and reversible anticoagulant for the prevention of heart attacks, strokes, and deaths due to blood clots in patients with rare cardiovascular conditions.

Tecarfarin is a vitamin K antagonist (VKA) potentially representing the first new therapeutic innovation in 70 years in VKA anticoagulation. Tecarfarin is designed to be a superior and

safer chronic oral anticoagulant therapy compared to warfarin for patients with implanted cardiac devices or rare cardiovascular conditions.

Cadrenal Therapeutics' drug candidate, tecarfarin, is expected to enter its pivotal Phase 3 trial during 2025. The Company's clinical program for tecarfarin is supported by extensive data demonstrating the molecule's potential as an alternative to warfarin, with safety data indicating fewer adverse events such as strokes, heart attacks, bleeds, and deaths in comparison with warfarin. The FDA granted tecarfarin orphan drug designation (ODD) for heart failure patients with implanted left ventricular assist devices (LVADs) as well as both ODD and Fast Track designation for end-stage kidney disease (ESKD) patients with atrial fibrillation (AFib).

For more information, please visit www.cadrenal.com and connect with the company on LinkedIn.

**Safe Harbor**

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 initiation of the pivotal Phase 3 clinical trial for tecarfarin in LVAD in 2025; providing updates on the anticipated trial in Q1 2025; continuing exploration of collaborations with potential development partners to advance tecarfarin's pivotal clinical trial for patients with LVAD and other rare cardiovascular conditions; joining the Corporate Council of the Anticoagulation Forum enabling the Company to collaborate with anticoagulation therapy thought leaders and 15,000 healthcare professionals to improve anticoagulation outcomes for patients globally; and the potential of tecarfarin, if approved, to provide a safer alternative to LVAD patients. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "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 initiate the pivotal Phase 3 clinical trial for tecarfarin in LVAD patients in 2025 and provide trial updates as planned; the ability to enter into collaborations with development partners; the ability of tecarfarin to provide a safer alternative to LVAD patients 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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