Cadrenal Therapeutics Expands Evaluation of Tecarfarin for Patients with Antiphospholipid Syndrome (APS)

NEW YORK, Aug. 30, 2023 — **Cadrenal Therapeutics, Inc.**, (Nasdaq: CVKD) a biopharmaceutical company developing tecarfarin, a late-stage novel oral and reversible anticoagulant (blood thinner) to prevent heart attacks, strokes and deaths due to blood clots in patients with certain rare medical conditions, today announced the expanded evaluation of tecarfarin for the treatment of patients with antiphospholipid syndrome (APS) who require chronic anticoagulation.



APS, formerly known as Hughes Syndrome or Sticky Blood in the United Kingdom, is a disorder of the immune system that causes an increased risk of blood clots. Normally, antibodies protect a person's body from viruses, bacteria, etc., but in APS, antibodies attack the body's healthy cells. High levels of APS antibodies raise the risk of blood clots. The specific antibodies in APS are called 'antiphospholipids' because they attack and damage parts of cells called phospholipids. The damage increases the chance that blood clots will form in both veins and arteries. Patients with APS who receive direct oral anticoagulants (DOACs) may have an increased risk for arterial thrombosis compared with those who receive Vitamin K antagonists (VKAs) such as warfarin, according to a study in the Journal of the American College of Cardiology.

"Antiphospholipid syndrome is a rare medical condition and blood clotting disorder affecting approximately 167,000 patients in the United States which currently has no cure. Effective anticoagulation (with blood thinners) should prevent health problems caused by the condition with the goal of treatment to prevent blood clots from forming and to keep existing clots from getting larger," commented Douglas Losordo, Chief Medical Officer of Cadrenal Therapeutics. "However, the only widely prescribed anticoagulant approved for this patient population is warfarin, a 70-year-old drug, which fails to achieve sufficiently reliable anticoagulation due to the way in which it is metabolized. We believe tecarfarin, which is specifically designed to solve warfarin's metabolism problem by using an alternate pathway, could provide improved outcomes for this patient population. Tecarfarin's metabolic pathway is abundant and essentially insaturable, which results in a reliable, stable pharmacokinetic profile."

Based on clinical data, market research, and insights from key industry experts, the Company believes tecarfarin is ideally positioned to target rare medical conditions where warfarin fails

to achieve sufficiently stable anticoagulation and Direct Oral Anticoagulants (DOACs) are not widely prescribed. Currently, Cadrenal has identified three such rare medical conditions: End-Stage Kidney Disease (ESKD) with Atrial Fibrillation (AFib); Left Ventricular Assist Devices (LVADs); and Antiphospholipid Syndrome (APS). Based on management's market analysis studies and expected adoption rates, these three rare medical conditions present a U.S. market opportunity in excess of \$2 billion per year. Currently, tecarfarin has orphan drug and Fast Track designations for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end-stage renal disease, and atrial fibrillation providing for 7year marketing exclusivity.

ABOUT CADRENAL THERAPEUTICS, INC.

Cadrenal Therapeutics is developing tecarfarin, a late-stage novel oral and reversible anticoagulant (blood thinner), to prevent heart attacks, strokes, and deaths due to blood clots in patients with certain rare medical conditions. Tecarfarin has orphan drug and Fast Track designations for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end-stage renal disease, and atrial fibrillation. Tecarfarin is specifically designed to leverage a different metabolism pathway than the oldest and most commonly prescribed Vitamin K antagonist (warfarin) used in the prevention of thrombosis. 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 chronic kidney disease. 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."

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 forwardlooking statements contain these identifying words. These statements include statements regarding patients with APS who receive direct oral anticoagulants (DOACs) having an increased risk for arterial thrombosis compared with those who receive Vitamin K antagonists (VKAs); effective anticoagulation (blood thinners) preventing health problems; tecarfarin being ideally positioned to target rare medical conditions where warfarin fails to achieve sufficiently stable anticoagulation and Direct Oral Anticoagulants (DOACs) are not widely prescribed; tecarfarin providing improved outcomes for patients with APS; and End Stage Kidney Disease (ESKD) with Atrial Fibrillation (AFib); Left Ventricular Assist Devices (LVADs); and Antiphospholipid Syndrome (APS) presenting at U.S. market opportunity in excess of \$2

billion.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the ability to successfully advance tecarfarin for the treatment of rare medical conditions including patients with APS who require chronic anticoagulation; the ability to assess the size of the U.S. market opportunity for patients with End Stage Kidney Disease (ESKD) with Atrial Fibrillation (AFib); Left Ventricular Assist Devices (LVADs); and Antiphospholipid Syndrome (APS) and the other 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 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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