Cadrenal Therapeutics to File for FDA Rare Pediatric Disease Designation for Tecarfarin in Kawasaki Disease

Company to present Phase 3-ready pipeline, 12-LOX platform, and pediatric rare-disease expansion to global pharmaceutical partners at the 2026 BIO International Convention in San Diego

Kawasaki disease is the leading cause of acquired heart disease in children in developed nations. Patients are at risk of forming blood clots in coronary arteries and may require lifelong treatment

If the designation is granted and tecarfarin is approved for this indication, Cadrenal would be eligible to receive a Priority Review Voucher-recent open-market valuations for these vouchers have reached into the ~$200 million range

PONTE VEDRA, Fla., June 18, 2026 (GLOBE NEWSWIRE) — Cadrenal Therapeutics, Inc. (Nasdaq: CVKD), a biopharmaceutical company advancing late-stage novel therapies for life-threatening immune and thrombotic conditions, today announced plans to submit a Rare Pediatric Disease Designation (RPDD) request to the U.S. Food and Drug Administration (FDA) for tecarfarin as a treatment for pediatric patients with Kawasaki disease (KD) who develop coronary artery aneurysms (CAAs) and require chronic oral anticoagulation.

The announcement comes ahead of the BIO International Convention, June 22-25, 2026, in San Diego, California. Cardenal's executive leadership team will highlight this rare pediatric initiative and its Phase 3-ready CAD-1005 platform during one-on-one partnering meetings with global and regional pharmaceutical companies.

KD is an acute inflammatory illness and the leading cause of acquired heart disease in children in developed nations. Up to 25% of untreated children with KD develop enlarged coronary arteries or CAAs. Patients with large CAAs are at risk for forming blood clots in those blood vessels – with a continuing lifelong risk for subsequent heart attacks and sudden cardiac death – and require chronic, precise anticoagulation therapy to reduce their higher risk of clot formation.

Tecarfarin is a novel, next-generation Vitamin K antagonist (VKA) that offers a number of potential advantages over warfarin, the current standard VKA in clinical use. Specifically, tecarfarin is designed to overcome limitations of warfarin metabolism and potentially provide more reliable and more consistent anticoagulation than might be possible with warfarin.

"Children with large or giant aneurysms due to KD represent an important underserved orphan population," said Quang X. Pham, Chief Executive Officer of Cadrenal Therapeutics. "The current standard of care – warfarin – is notoriously unstable in children because of dietary variations, concurrent medications, and genetic differences in liver metabolism.

Tecarfarin is metabolized in a completely different way than warfarin, and is being developed to offer a highly stable, predictable alternative. We believe tecarfarin can potentially improve time in therapeutic range for these children, thereby lowering their risk for both catastrophic blood clots and dangerous bleeding events."

The FDA's RPDD program targets serious or life-threatening diseases that primarily affect fewer than 200,000 people in the United States from birth through age 18. If the FDA grants the designation and tecarfarin is subsequently approved for this indication, Cadrenal would be eligible to receive a Priority Review Voucher (PRV). These transferable vouchers can be used to accelerate the FDA review of a future drug or sold to another pharmaceutical manufacturer. Following Congress's extension of the pediatric PRV program through September 30, 2029, recent open-market valuations for these vouchers have reached record highs, with recent sales ranging from $180 million to $205 million.

At the upcoming BIO International Convention, Cadrenal will present a dual-track portfolio strategy designed to maximize value for potential partners:

- The Global Pharma Track: Focusing on CAD-1005, a first-in-class 12-LOX inhibitor. CAD-1005 is Phase 3-ready for Heparin-Induced Thrombocytopenia (HIT) and is advancing into a Phase 2a trial for Cardiac Surgery-Associated Acute Kidney Injury (CSA-AKI), addressing a combined, multi-billion-dollar dual-indication acute hospital care market.
- The Regional & Rare Disease Track: Focusing on tecarfarin for Kawasaki disease. This program offers an efficient clinical trial design and strong geographic synergy, particularly for Japanese and East Asian pharmaceutical companies, where the incidence of Kawasaki disease is historically 10 to 15 times higher than in Western nations.

"Our presence at BIO 2026 centers on executing capital-efficient development strategies," added Mr. Pham. "If we are successful in advancing tecarfarin toward a RPDD, we will create a high-value, de-risked regulatory pathway that aligns with regional partners' portfolio needs while directing our core internal resources toward our blockbuster CAD-1005 critical care franchise."

About Cadrenal Therapeutics, Inc.
Cadrenal Therapeutics is a biopharmaceutical company advancing late-stage novel therapies for life-threatening immune and thrombotic conditions. The company's pipeline includes CAD-1005, a novel first-in-class 12-LOX inhibitor targeting multiple critical care indications, and tecarfarin, a late-stage oral anticoagulant designed to avoid CYP450 metabolism. CAD-1005 has received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration, as well as orphan drug status from the European Medicines Agency, for the treatment of Heparin-Induced Thrombocytopenia (HIT). CAD-1005 is also being developed

for use in Cardiac Surgery-Associated Acute Kidney Injury (CSA-AKI), and second-generation 12-LOX oral therapeutics are in development for chronic indications.

About Tecarfarin

The Company's broader pipeline includes tecarfarin, a late-stage oral vitamin K antagonist designed to prevent heart attacks, strokes, and deaths from blood clots in patients requiring chronic anticoagulation, including those with end-stage kidney disease and those with left ventricular assist devices. Tecarfarin has also received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration.

Safe Harbor Statement

Any 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." 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. These statements include, without limitation, statements regarding plans to file for FDA Rare Pediatric Disease Designation for Tecarfarin in Kawasaki Disease; Cadrenal being eligible to receive a Priority Review Voucher and the value of the voucher*;* tecarfarin offering a number of potential advantages over warfarin, tecarfarin overcoming limitations of warfarin metabolism and potentially providing more reliable and more consistent anticoagulation than might be possible with warfarin; tecarfarin offering a highly stable, predictable alternative to warfarin; tecarfarin potentially improving time in therapeutic range for these children, thereby lowering their risk for both catastrophic blood clots and dangerous bleeding events and the successful advancement of tecarfarin creating a high-value, de-risked regulatory pathway that aligns with regional partners' portfolio needs while directing the Company's core internal resources toward its CAD-1005 critical care franchise Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the ability to raise sufficient capital to continue progress of CAD-1005; the ability for tecarfarin to receive a Rare Pediatric Disease Designation for treatment of Kawasaki Disease; the ability to monetize a priority review voucher if received, the ability to successfully design and complete a dual-track portfolio strategy and maximize value for potential partners; the ability of tecarfarin to overcome limitations of warfarin metabolism and potentially provide more reliable and more consistent anticoagulation than might be possible with warfarin; the ability of tecarfarin offering a highly stable, predictable alternative to warfarin; tecarfarin potentially improving time in therapeutic range for children with Kawasaki Disease, thereby lowering their risk for both catastrophic blood clots and dangerous bleeding events and the successful advancement of tecarfarin creating a high-value, de-risked regulatory pathway that aligns with regional partners' portfolio needs; ; the

ability to successfully design and complete the Phase 3 study and derive the results needed for an NDA submission: and the other risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, 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.

For more information, visit https://www.cadrenal.com/ and connect with the Company on LinkedIn.

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