Cadrenal Therapeutics Announces Upcoming Type-B FDA Meeting in September to Discuss Tecarfarin Trial in LVAD Patients

PONTE VEDRA, Fla., Aug. 22, 2024 — Cadrenal Therapeutics, Inc. (Nasdaq: CVKD), a biopharmaceutical company developing tecarfarin, a late-stage, next-generation Vitamin K Antagonist (VKA) oral and reversible anticoagulant (blood thinner) designed to prevent heart attacks, strokes, and deaths due to blood clots in patients with implanted cardiac devices and those with rare cardiovascular conditions, announced today that it will be engaging with the U.S. Food and Drug Administration (FDA) in early September for a Type-B meeting to discuss its clinical trial for tecarfarin in LVAD patients.

“This upcoming meeting with the FDA is a crucial step in developing tecarfarin as we prepare for our pivotal trial. We look forward to discussing the development program for tecarfarin in LVAD patients,” said Quang Pham, Chief Executive Officer of Cadrenal Therapeutics.

ABOUT LVAD PATIENTS

Left Ventricular Assist Devices (LVADs) are mechanical pumps to support heart function in patients with advanced heart failure. These devices are vital for patients awaiting heart transplants or those who are ineligible for transplants. However, LVAD patients face an increased risk of thromboembolic events, such as strokes, which necessitates ongoing anticoagulation therapy. The current anticoagulation therapy, warfarin, presents challenges, including variability in dosing, a narrow therapeutic window, and potential interactions with other medications, making effective management crucial to reducing complications and ensuring patient safety.

ABOUT CADRENAL THERAPEUTICS, INC.
Cadrenal Therapeutics is developing tecarfarin for unmet needs in anticoagulation therapy. Tecarfarin is a late-stage novel oral and reversible anticoagulant (blood thinner) to prevent heart attacks, strokes, and deaths due to blood clots in patients with implanted cardiac devices and those with rare cardiovascular conditions. Tecarfarin has orphan drug designation for the prevention of thrombosis and thromboembolism in patients with ventricular assist devices. Tecarfarin also has orphan drug and fast-track designations from the FDA for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end-stage kidney disease and atrial fibrillation. Cadrenal is also pursuing

additional regulatory strategies for unmet needs in anticoagulation therapy for patients with thrombotic antiphospholipid syndrome (APS). Tecarfarin is specifically designed to leverage a different metabolism pathway than the oldest and most commonly prescribed Vitamin K Antagonist (warfarin). Tecarfarin has been evaluated in 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.” These statements include statements regarding the Company engaging with the FDA in early September for a Type-B meeting to discuss its clinical trial for tecarfarin in LVAD patients and the planned pivotal trial. 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 success of the Type-B meeting, the ability of the Company to commence and complete a pivotal trial and commercialize tecarfarin with patients with left ventricular assist devices (LVADs), 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 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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View original content to download multimedia:https://www.prnewswire.com/news-releases/cadrenal-therapeutics-announces-upcoming-type-b-fda-meeting-in-september-to-discuss-tecarfarin-trial-in-lvad-patients-302228174.html

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