Armetheon Announces Positive Tecarfarin Clinical Data to Be Presented at the European Society of Cardiology (ESC) Congress

Armetheon Planning Phase 3 Pivotal Tecarfarin for AntiCoagulation Trial (TACT)

MILPITAS, Calif., Aug. 23, 2016 /PRNewswire/ -- Armetheon, Inc., a specialty pharmaceutical company developing novel small molecule drugs for cardiovascular diseases, today announced that positive clinical findings for tecarfarin, the Company's novel vitamin K antagonist (VKA) in Phase 3 development, will be presented at the upcoming ESC Congress 2016, taking place in Rome, Italy, August 27 - 31, 2016. Results will be highlighted from five clinical trials, which enrolled a combined total of 742 patients requiring anticoagulation and 136 healthy volunteers:

- One presentation (poster abstract #P3811) will review safety findings for tecarfarin used to provide anticoagulation for up to one year in 51 patients with a mechanical heart valve. Also featured will be results demonstrating the ability to readily reverse tecarfarin activity with vitamin K or fresh frozen plasma.
- A second presentation (poster abstract # P3144) will report on tecarfarin's pharmacokinetics and pharmacodynamics. Tecarfarin was shown to be a potent vitamin K antagonist with effects on coagulation parameters similar to those of warfarin for any given level of INR (International Normalized Ratio).

Richard P. Whitlock, MD, PhD, a trial principal investigator and Associate Professor, Department of Cardiac Surgery, McMaster University, Ontario, Canada, commented, "As a novel oral VKA, tecarfarin differs from warfarin by avoidance of CYP2C9 metabolism, sparing tecarfarin from genetic variations in CYP2C9 metabolism and from drug interactions in a patient population that often requires the use of multiple concomitant medications. This should result in more predictable and stable levels of anticoagulation. I believe tecarfarin can become a welcome new treatment, particularly for mechanical heart valve recipients who have no current alternatives to warfarin."

Sanjay Kakkar, MD, Armetheon's Chief Executive Officer, stated, "It is gratifying to see the important findings of clinical studies of tecarfarin conducted by leading researchers being presented at a major international cardiology meeting. Based on the promising clinical results we've seen to date, we are making preparations for the final pivotal Phase 3 clinical registration study of tecarfarin, in diverse patient groups, including patients with valvular diseases and those with chronic kidney disease."

Armetheon's Tecarfarin Presentations at the ESC Congress 2016

Abstract Title (abstract #P3811): Experience with tecarfarin, a novel vitamin K antagonist: Use with reversing agents and in mechanical heart valve recipients
Presenting Author: Mark G. Midei, M.D., Armetheon, Inc.
Session Title: Poster Session 4: Thrombosis and coagulation
Presentation Time and Date: 8:30 am - 12:30 pm CEST, Monday, August 29, 2016
Location: Poster Area, Fiera Di Roma

Abstract Title (abstract # P3144): Tecarfarin pharmacokinetics and pharmacodynamics-A novel CYP2C9 independent vitamin K antagonist
Presenting Author: Mark G. Midei, M.D., Armetheon, Inc.
Session Title: Poster Session 4: Thrombosis and coagulation; Moderated Poster Session: Insights on thrombosis and anticoagulants
Presentation Time and Date: Poster: 8:30 am - 12:30 pm CEST, Monday, August 29, 2016; Moderated Presentation: 10:40 am CEST, Monday, August 29, 2016
Location: Moderated Poster Station – Poster Area, Fiera Di Roma

About Tecarfarin
Tecarfarin is being investigated for use as an oral, once-daily anticoagulant that inhibits Vitamin K epoxide reductase (VKOR), an important enzyme in the coagulation system, and avoids CYP450 metabolism and renal elimination. In Phase 2 and Phase 2/3 (EMBRACE-AC) clinical testing, tecarfarin improved time in therapeutic range (TTR) in chronically anticoagulated patients. The effect of tecarfarin on TTR will be further investigated in the Company's upcoming pivotal clinical trial, TACT (Tecarfarin for AntiCoagulation Trial), which will be conducted under a Special Protocol Assessment agreed upon with the FDA. TACT is an open-label trial expected to enroll 3,000 patients with any indication for anticoagulation, including prosthetic heart valve (PHV) patients. TTR was chosen as the primary endpoint for TACT on the basis of evidence suggesting that better anticoagulation control (as measured by higher TTR) can protect patients from severe or even fatal adverse events. Tecarfarin is monitored using INR (International Normalized Ratio) and is being investigated for use without the need for CYP2C9 genotyping since tecarfarin is not metabolized via the CYP450 system. In preclinical and early clinical studies, the anticoagulant effect of tecarfarin was reversed by existing and readily available antidotes for Vitamin K Antagonists.

About Armetheon
Armetheon, Inc., is a privately held, specialty pharmaceutical company developing and commercializing innovative medicines addressing major unmet needs in cardiovascular disease, initially in thrombosis and cardiac arrhythmias. Armetheon focuses on improved therapies with the goal of increased efficacy, safety, and utility, targeting specialty markets with clearly defined regulatory pathways. Armetheon's lead candidate, tecarfarin, is being investigated for use as a Vitamin K Antagonist and is currently in Phase 3 development for the prevention and management of thrombosis. Armetheon is also developing its anti-arrhythmic drug candidate, budiodarone, for the treatment of ventricular tachycardia (VT) in patients with implantable cardioverter defibrillators (ICDs). For more information: www.armetheon.com.

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