



C A R D I O M E



**FOR IMMEDIATE RELEASE NASDAQ: CRME TSX: COM**

**FDA ADVISORY COMMITTEE RECOMMENDS**  
**APPROVAL OF KYNAPID™ FOR ACUTE ATRIAL**  
**FIBRILLATION**

**Vancouver, Canada and Deerfield, Illinois, USA, December 11, 2007** -- Cardiome Pharma Corp. (NASDAQ: CRME / TSX: COM) and its co-development partner Astellas Pharma US, Inc. (“Astellas”) today announced that the Cardiovascular and Renal Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has recommended that the FDA approve KYNAPID™, the intravenous formulation of vernakalant hydrochloride, an investigational new drug for rapid conversion of acute atrial fibrillation (AF).

At the panel review conducted today in Maryland, the members voted 6 to 2 in favour of recommending to the FDA that KYNAPID be approved for the rapid conversion of acute AF to sinus rhythm. If approved, KYNAPID will be the first new pharmacologic therapy for the conversion of AF in eight years.

“We are pleased with the committee’s recommendation,” said William E. Fitzsimmons, PharmD, Senior Vice President, Research & Development at Astellas. “We strongly believe in the therapeutic value of KYNAPID based on clinical trial data and are confident it will be an important therapy for people with atrial fibrillation.”

“We welcome the committee’s recommendation for approval, and look forward to the FDA completing their review and acting on the application early in the new year,” stated Bob Rieder, Chief Executive Officer and Chairman of Cardiome. “People with atrial fibrillation suffer significant disease burden, and we are pleased to move an important step closer to providing doctors with an important tool for meeting this critical unmet medical need.”

The Cardiovascular and Renal Drugs Advisory Committee is convened on request of the FDA, and reviews and evaluates available data concerning the safety and effectiveness of human drug products for use in the treatment of cardiovascular and renal disorders. Although the Committee provides recommendations to the Agency and suggests a course of action, final decisions are made by the FDA. An action further to the FDA review of KYNAPID is expected on or before January 19, 2008.

KYNAPID is the proposed brand name in North America for the intravenous formulation vernakalant hydrochloride, and has been provisionally accepted by the FDA. Final approval of provisionally accepted names is granted upon approval of the investigational drug. The NDA for KYNAPID, based on a five-year clinical development program, was submitted in December 2006 and accepted for review by the FDA in February 2007.

In October 2003, Cardiome granted Astellas Pharma US, Inc. an exclusive license to develop and commercialize KYNAPID in North America. Cardiome has retained all rights to the intravenous formulations outside of Canada, the U.S. and Mexico. Upon approval, KYNAPID will be marketed in the United States by Astellas Pharma US, Inc., a U.S. affiliate of Astellas Pharma Inc.

## **About Atrial Fibrillation**

AF, the most common cardiac arrhythmia, is an interruption of the normal sinus rhythm (arrhythmia) of the heart in which the atria, the two uppermost chambers of the heart, beat irregularly and at an extremely rapid rate. During AF, rapid and uncoordinated electrical discharges are generated by the heart's natural pacemaker (sinoatrial node) and other parts of the atria. This causes ineffective contractions of the atria and reduces the ability of the heart to pump blood through the body. Symptoms include dizziness, heart palpitations, weakness, shortness of breath and angina (chest pain). If AF is left undiagnosed or untreated, life-threatening complications such as stroke can occur.<sup>1</sup>

The number of AF patients is expected to increase dramatically over the next 50 years due to an aging population, and the increased prevalence of risk factors including hypertension, obesity, diabetes and sleep apnea.<sup>2</sup>

## **About Cardiome**

Cardiome Pharma Corp. is a product-focused cardiovascular drug development company with two late-stage clinical drug programs focused on atrial arrhythmia (intravenous and oral dosing), a Phase 1 program for GED-aPC, an engineered analog of recombinant human activated Protein C, and a pre-clinical program directed at improving cardiovascular function.

Vernakalant (iv) is the intravenous formulation of an investigational drug being evaluated for the acute conversion of atrial fibrillation. Positive top-line results from two pivotal Phase 3 trials for vernakalant (iv), called ACT 1 and ACT 3, were released in December 2004 and September 2005. Cardiome's co-development partner Astellas Pharma US, Inc. submitted a New Drug Application for vernakalant (iv) in December 2006. Positive top-line results from an additional Phase 3 study evaluating patients with post-operative atrial arrhythmia, called ACT 2, were released in June 2007. An open-label safety study evaluating recent-onset AF patients, called ACT 4, has completed.

Vernakalant (oral) is being investigated as a chronic-use oral drug for the maintenance of normal heart rhythm following termination of AF. Cardiome announced positive results from a Phase 2a pilot study for vernakalant (oral) in September 2006. A Phase 2b study for vernakalant (oral) is ongoing.

In April 2007 Cardiome acquired exclusive worldwide rights for GED-aPC for all indications. Cardiome intends to initially develop GED-aPC in cardiogenic shock, a life-threatening form of acute circulatory failure due to cardiac dysfunction, which is a leading cause of death for patients hospitalized following a heart attack.

Cardiome is traded on the Toronto Stock Exchange (COM) and the NASDAQ National Market (CRME).

## **About Astellas**

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities.

In the US, Astellas markets products in the areas of Immunology, Urology, Anti-Infectives, Cardiovascular and Dermatology. For more information about Astellas Pharma US, Inc., please visit our website at [www.astellas.com/us](http://www.astellas.com/us).

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2. Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular Trends in Incidence of Atrial Fibrillation in Olmsted County, Minnesota, 1980 to 2000, and Implications on the Projections for Future Prevalence. *Circulation* 2006;114:119-125.

**Forward-Looking Statement Disclaimer**

Certain statements in this press release contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 or forward-looking information under applicable Canadian securities legislation that may not be based on historical fact, including without limitation statements containing the words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect” and similar expressions. Such forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any future results, events or developments expressed or implied by such forward-looking statements or information. Such factors include, among others, our stage of development, lack of product revenues, additional capital requirements, risk associated with the completion of clinical trials and obtaining regulatory approval to market our products, the ability to protect our intellectual property, dependence on collaborative partners and the prospects for negotiating additional corporate collaborations or licensing arrangements and their timing. Specifically, certain risks and uncertainties that could cause such actual events or results expressed or implied by such forward-looking statements and information to differ materially from any future events or results expressed or implied by such statements and information include, but are not limited to, the risks and uncertainties that: we may not be able to successfully develop and obtain regulatory approval for vernakalant (iv) or vernakalant (oral) in the treatment of atrial fibrillation or any other current or future products in our targeted indications; our future operating results are uncertain and likely to fluctuate; we may not be able to raise additional capital; we may not be successful in establishing additional corporate collaborations or licensing arrangements; we may not be able to establish marketing and sales capabilities and the costs of launching our products may be greater than anticipated; we rely on third parties for the continued supply and manufacture of vernakalant (iv) and vernakalant (oral) and we have no experience in commercial manufacturing; we may face unknown risks related to intellectual property matters; we face increased competition from pharmaceutical and biotechnology companies; and other factors as described in detail in our filings with the Securities and Exchange Commission available at [www.sec.gov](http://www.sec.gov) and the Canadian securities regulatory authorities at [www.sedar.com](http://www.sedar.com).

Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements and information, which are qualified in their entirety by this cautionary statement. All forward-looking statements and information made herein are based on our current expectations and we undertake no obligation to revise or update such forward-looking statements and information to reflect subsequent events or circumstances, except as required by law.

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