



## News Release

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### FOR IMMEDIATE RELEASE

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### **Merck and Cardiome Announce Phase III Study Results Comparing Investigational Compound Vernakalant Intravenous to Amiodarone Injection in Conversion of Atrial Fibrillation to Normal Sinus Rhythm**

#### **Data Presented During Late-Breaking Clinical Trials Session at the Heart Rhythm Society (HRS) Annual Meeting**

DENVER, CO, USA, MAY 14, 2010 – In a new Phase III study, vernakalant intravenous, an investigational compound being developed in the European Union by Merck (known as MSD outside the USA and Canada) (NYSE: MRK) and Cardiome Pharma Corp. (NASDAQ: CRME / TSX: COM) to treat atrial fibrillation, showed that vernakalant intravenous was superior to amiodarone injection, in converting patients' heart rate from atrial fibrillation (AF) to sinus rhythm (SR) within 90 minutes of the start of administration. The results of the study were presented May 14th during a late-breaking clinical trials session at Heart Rhythm 2010, the annual meeting of the Heart Rhythm Society.

In the study, called AVRO (Active-Controlled, Multi-Center Study of Vernakalant Injection versus Amiodarone in Subjects with Recent Onset Atrial Fibrillation), 51.7 percent (n=116) of patients on vernakalant intravenous converted from atrial fibrillation to normal sinus rhythm within 90 minutes, versus 5.2 percent (n=116) in the amiodarone group (p<0.0001). The median time to conversion in patients who responded to vernakalant intravenous was 11 minutes.

"Atrial fibrillation is the most common abnormal heart rhythm and its prevalence has increased over the past 20 years. It is important to have therapies that convert patients back to a normal heart rhythm as quickly as possible," says John Camm, BSc, M.D., FRCP, professor of Clinical Cardiology at St George's, University of London and lead investigator of the AVRO study. "The efficacy and safety results of vernakalant in this study are encouraging."

### **About the AVRO study**

This phase III randomized, double blind, active controlled, double dummy, multi-center trial enrolled a total of 254 patients with symptomatic atrial fibrillation of 3 to 48 hours duration of which 232 were randomized to receive an infusion of either vernakalant intravenous, n=116 (3 mg/kg over 10 minutes; followed by 2 mg/kg over 10 minutes if needed after a 15-minute break) or amiodarone, n=116 (5 mg/kg over 60 minutes, followed by 50 mg over 60 minutes).

The primary endpoint of the AVRO study was the proportion of patients with conversion to SR within 90 minutes. The secondary endpoints were (1) time to conversion of SR within 90 minutes; (2) proportion of patients without AF symptoms at 90 minutes; and (3) change in quality of life, assessed at hour two using a 100-point visual analogue scale (VAS). Safety was assessed through the monitoring of adverse events, vital signs, continuous telemetry monitoring, 12-lead Holter monitoring, 12-lead ECGs, and laboratory tests.

Data on the secondary endpoint showed that 53.4 percent of patients (n=116) in the vernakalant intravenous group had no AF symptoms at 90 minutes versus 32.8 percent in the amiodarone (n=116) group (p=0.0012). There was also a significant improvement in quality of life (p=.0006) in the vernakalant intravenous group, n=116, (10.9 point increase) compared to the amiodarone group, n=116, (5.6 point increase). Quality of life was assessed at screening and two hours after the start of infusion using the EQ-5D Health Questionnaire. The EQ-5D is a standardized instrument, self-completed by respondents, used to measure health outcomes.

The most common adverse events within 24 hours of infusion (> 2 events in either group) were dysgeusia (bad taste in mouth) which occurred in 6.9 percent of patients on vernakalant intravenous (n=116) versus zero on amiodarone (n=116); cough (3.4 percent on vernakalant intravenous vs. 1.7 percent on amiodarone); sneezing (3.4 percent on vernakalant intravenous vs. zero on amiodarone); atrial fibrillation (3.4 percent on vernakalant intravenous vs. zero on amiodarone); nausea (2.6 percent on vernakalant intravenous vs. 1.7 percent on amiodarone); dizziness (2.6 percent in both the vernakalant intravenous and amiodarone groups); and hypertension (2.6 percent on vernakalant intravenous vs. zero on amiodarone).

### **About vernakalant**

Vernakalant is an investigational compound being developed in two formulations, oral and IV, for the treatment of atrial fibrillation. Vernakalant in the intravenous (IV) formulation is currently under review in the European Union (EU). Vernakalant in the oral formulation is being developed for daily maintenance of normal heart rhythm in patients with atrial fibrillation to prevent reoccurrence of atrial fibrillation and is currently in Phase II development.

In April 2009, Cardiome and Merck announced a collaboration and license agreement for the development and commercialization of vernakalant. The agreement provides a Merck affiliate, Merck Sharp & Dohme Corp., with exclusive global rights to vernakalant oral, and provides another Merck affiliate, Merck Sharp & Dohme (Switzerland) GmbH, with exclusive rights outside of the United States, Canada and Mexico to vernakalant IV.

Vernakalant is not available in Canada.

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. Merck. Be well. For more information, visit [www.merck.com](http://www.merck.com).

### **About Cardiome Pharma Corp.**

Cardiome Pharma Corp. is a product-focused drug development company dedicated to the advancement and commercialization of novel treatments for disorders of the heart and circulatory system. Cardiome is traded on the NASDAQ Global Market (CRME) and the Toronto Stock Exchange (COM). For more information, please visit our web site at [www.cardiome.com](http://www.cardiome.com).

### **Merck Forward Looking Statement**

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the proposed merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's and Schering-Plough's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time

period, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2008 Annual Report on Form 10-K, Schering-Plough's Quarterly Report on Form 10-Q for the quarterly period ended Sept. 30, 2009, the proxy statement filed by Merck on June 25, 2009 and each company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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### **Cardiome Forward Looking Statement**

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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