



# FOR IMMEDIATE RELEASE NASDAQ: CRME TSX: COM

# CARDIOME AND ASTELLAS ANNOUNCE RECEIPT OF FDA APPROVABLE LETTER FOR KYNAPID<sup>TM</sup>

Vancouver, Canada and Deerfield, Illinois, USA, August 11, 2008 -- Cardiome Pharma Corp. (NASDAQ: CRME / TSX: COM) and its co-development partner Astellas Pharma US, Inc. ("Astellas") today announced that they have received an action letter dated August 8, 2008 from the U.S. Food and Drug Administration (FDA) for KYNAPID<sup>TM</sup> (vernakalant hydrochloride) Injection for the treatment of atrial fibrillation (AF) – a potentially life-threatening condition that occurs when electrical signals in the heart malfunction. KYNAPID is under review for the rapid conversion of AF to sinus rhythm.

In the action letter, the FDA informed the sponsor (Astellas) that it has completed its review of the KYNAPID NDA and that the application is approvable. Prior to considering approval, FDA requires additional information associated with the risk of previously identified events experienced by a subset of patients during the clinical trials in order to assure an acceptable risk benefit profile compared to electrical cardioversion. FDA has also requested a safety update from ongoing or completed studies of vernakalant, regardless of indication, dosage form, or dose level. Cardiome and Astellas will work closely with the FDA to address all issues raised in the approvable letter.

"Astellas will be in contact with the FDA within the next few days to discuss next steps, and we expect that several months may be required to assemble a complete and appropriate response," stated Bob Rieder, Chief Executive Officer and Chairman of Cardiome. "While this action letter could result in the need for an additional clinical study, Cardiome is optimistic that the questions raised can be satisfactorily addressed from currently available data."

"Astellas and Cardiome strongly believe in the therapeutic value of KYNAPID based on clinical trial data and are confident it will be an important therapy in the treatment of atrial fibrillation," said William E. Fitzsimmons, PharmD, Senior Vice President, Research & Development at Astellas.

In October 2003, Cardiome granted Astellas Pharma US, Inc. an exclusive license to develop and commercialize KYNAPID in North America. Cardiome retains worldwide rights to vernakalant (oral) for the prevention of AF recurrence and all rights to the intravenous formulations outside of Canada, U.S. and Mexico. The NDA for KYNAPID, based on a five-year clinical development program, was submitted in December 2006.

# **About Cardiome**

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 National Market (CRME) and the Toronto Stock Exchange (COM). For more information, please visit our web site at www.cardiome.com.

#### 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 <a href="https://www.astellas.com/us">www.astellas.com/us</a>.

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## 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 and the Canadian securities regulatory authorities at 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.