



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

## **CARDIOME ANNOUNCES FILING OF ORPHAN DRUG APPLICATION FOR ORAL VERNAKALANT WITH U.S. FDA**

**Vancouver, Canada, January 27, 2016** -- Cardiome Pharma Corp. (NASDAQ: CRME / TSX: COM) today announced that it has filed with the FDA's Office of Orphan Products Development (OOPD) a request for orphan drug designation for an oral formulation of vernakalant hydrochloride, under the FDA's Orphan Drug Act (ODA). The indication listed within the application is the prevention of post-operative atrial fibrillation in patients undergoing coronary artery bypass graft surgery.

To qualify for orphan designation, both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations at 21 CFR Part 316, principal of which is that the disease or condition must affect fewer than 200,000 persons in the United States, that the medical needs of these patients are failing to be satisfied by currently available treatment options and that the drug in question has the potential to provide benefit.

The OOPD's target is to respond to the request within 90 days. If successful, Cardiome anticipates discussing an appropriate development plan for oral vernakalant in this orphan population with the FDA, utilising the various incentives that accompany such designation, including the waiver of various fees, tax incentives as well as improved post-approval market protections.

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

Cardiome Pharma Corp. is a specialty pharmaceutical company dedicated to the development and commercialization of cardiovascular therapies that will improve the quality of life and health of patients suffering from heart disease. Cardiome has two marketed, in-hospital, cardiology products, BRINAVESS<sup>®</sup> (vernakalant IV), approved in Europe and other territories for the rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults, and AGGRASTAT<sup>®</sup> (tirofiban HCl) a reversible GP IIb/IIIa inhibitor indicated for use in patients with acute coronary syndrome. Cardiome also commercializes Esmocard<sup>®</sup> and Esmocard Lyo<sup>®</sup> (esmolol hydrochloride), a short-acting beta-blocker used to control rapid heart rate in a number of cardiovascular indications, on behalf of their partner AOP Orphan Pharma in select European markets. Cardiome has also licensed TREVYENT<sup>®</sup>, a development stage drug device combination that is under development for Pulmonary Arterial Hypertension for Europe, the Middle East and for Canadian markets.

Cardiome is traded on the NASDAQ Capital Market (CRME) and the Toronto Stock Exchange (COM). For more information, please visit our web site at [www.cardiome.com](http://www.cardiome.com).

### **Forward-Looking Statement Disclaimer**

Certain statements in this news 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. Forward-looking statements may involve, but are not limited to, comments with respect to our objectives and priorities for the remainder of 2016 and beyond, our strategies or future actions, our targets, expectations for our financial condition and the results of, or outlook for, our operations, research and development and product and drug development. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Many such known risks, uncertainties and other factors are taken into account as part of our assumptions underlying these forward-looking statements and include, among others, the following: general economic and business conditions in the United States, Canada, Europe, and the other regions in which we operate; market demand; technological changes that could impact our existing products or our ability to develop and commercialize future products; competition; existing governmental legislation and regulations and changes in, or the failure to comply with,

governmental legislation and regulations; availability of financial reimbursement coverage from governmental and third-party payers for products and related treatments; adverse results or unexpected delays in pre-clinical and clinical product development processes; adverse findings related to the safety and/or efficacy of our products or products; decisions, and the timing of decisions, made by health regulatory agencies regarding approval of our technology and products; the requirement for substantial funding to expand commercialization activities; and any other factors that may affect our performance. In addition, our business is subject to certain operating risks that may cause any results expressed or implied by the forward-looking statements in this presentation to differ materially from our actual results. These operating risks include: our ability to attract and retain qualified personnel; our ability to successfully complete pre-clinical and clinical development of our products; changes in our business strategy or development plans; intellectual property matters, including the unenforceability or loss of patent protection resulting from third-party challenges to our patents; market acceptance of our technology and products; our ability to successfully manufacture, market and sell our products; the availability of capital to finance our activities; and any other factors 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, uncertainties and factors, 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.

### **For Further Information:**

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