



**CARDIOME**<sup>®</sup>  
PHARMA CORP.



**FOR IMMEDIATE RELEASE**

**CARDIOME AND STEADYMED ANNOUNCE  
DECISION FOR CENTRALIZED REVIEW OF TREVYENT<sup>®</sup>  
BY THE EUROPEAN MEDICINES AGENCY**

**VANCOUVER, Canada and SAN RAMON, Calif., January 6, 2016** – Cardiome Pharma Corp. (Nasdaq: CRME, TSX: COM) and SteadyMed Ltd. (Nasdaq: STDY), today announced that the European Medicines Agency (EMA) has approved Cardiome’s request to review Trevyent<sup>®</sup> (treprostinil PatchPump) under the Centralised Authorisation Procedure drug review process. This procedure results in a single marketing authorization that is valid in all 28 European Union (EU) countries as well as 3 European Economic Area (EEA) countries. Cardiome requested, and was granted, the centralized pathway on the basis that Trevyent<sup>®</sup> represents a significant technical innovation for the potential treatment of pulmonary arterial hypertension (PAH).

“We are pleased that the EMA has agreed to review Trevyent through the centralized review process,” said Jonathan Mather, Cardiome’s Director of Regulatory Affairs. “This will enable us to streamline the process of gaining a license in all member states of Europe, with the opportunity of providing those living with PAH quicker access to Trevyent.”

“Registration through the Centralized Procedure is typically reserved for products with significant therapeutic, scientific or technical innovation and reflects positively on the innovative approach we are taking to the potential treatment of PAH and the patient-friendly design of Trevyent,” stated Peter D. Noymer, Ph.D., Chief Technology Officer of SteadyMed. “I am very pleased with the EMA’s decision and its potentially positive impact on the lives of patients with this devastating disease.”

Cardiome and its affiliate, Correvio International Sárl, entered into an exclusive license and supply agreement for Trevyent with SteadyMed Ltd. in June 2015 that includes the territories of Europe, Canada and the Middle East. Trevyent is a development stage drug product candidate that combines SteadyMed’s PatchPump technology with treprostinil, a vasodilatory prostacyclin analogue, to treat PAH. SteadyMed intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration for Trevyent in the third quarter of 2016.

**About Pulmonary Arterial Hypertension**

Pulmonary arterial hypertension is a type of high blood pressure that occurs in the right side of the heart and in the arteries that supply blood to the lungs. PAH worsens over time and is life-threatening because the pressure in a patient's pulmonary arteries rises to dangerously high levels, putting a strain on the heart. There is no cure for PAH, but several medications are available to treat symptoms, such as the market-leading prostacyclin PAH therapy, Remodulin<sup>®</sup> (treprostinil sodium), which is produced by United Therapeutics Corporation. The annual cost of Remodulin is reported to be between approximately \$125,000 and \$175,000 per patient and United Therapeutics reported Remodulin revenues of \$554 million in 2014.

### **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 from SteadyMed Therapeutics Inc., TREVYENT<sup>®</sup> (treprostinil sodium), 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 about Cardiome please visit [www.cardiome.com](http://www.cardiome.com).

### **About SteadyMed**

SteadyMed Ltd. is a specialty pharmaceutical company focused on the development of drug products to treat orphan and high value diseases with unmet parenteral delivery needs. The company's lead drug product candidate is Trevyent<sup>®</sup>, a development stage drug product that combines SteadyMed's PatchPump technology with treprostinil, a vasodilatory prostacyclin analogue to treat pulmonary arterial hypertension (PAH). PatchPump is a proprietary, disposable, parenteral drug administration platform that is prefilled and preprogrammed at the site of manufacture. SteadyMed intends to commercialize Trevyent in the U.S. and has signed an exclusive license and supply agreement with Cardiome Pharma Corp. for the commercialization of Trevyent in Europe, Canada and the Middle East. SteadyMed has offices in San Ramon, California and Rehovot, Israel. For additional information about SteadyMed please visit [www.steadymed.com](http://www.steadymed.com).

### **Forward-Looking Statement Disclaimer (Cardiome)**

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.

### **Forward Looking Statements (SteadyMed)**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements concerning the company's ability to advance its development-stage product candidates, including Trevynt, statements about the potential benefits of our development-stage product candidates and our PatchPump technology, and statements about our ability to obtain and maintain regulatory approval of our development-stage product candidates. Forward-looking statements reflect the company's current views with respect to certain current and future events and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially. Risks and uncertainties include, but are not limited to, the risk that drug development involves a lengthy and expensive process with uncertain outcome. The risks, uncertainties and assumptions referred to above are discussed in detail in our reports filed with the Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q filed on November 12, 2015. The company does not undertake to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date hereof except as may be required by law.

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