Cardium Initiates Generx@ Phase 3 Clinical Registration Study

The Associated Press

Cardium Therapeutics (NYSE Amex: CXM) today announced the initiation of the ASPIRE Phase 3 registration study to evaluate the therapeutic effects of Cardium's lead product candidate, Generx@ (Ad5FGF-4) in patients with myocardial ischemia (insufficient blood flow in the heart due to coronary artery disease).

(Photo: http://photos.prnewswire.com/prnh/20120320/LA71801 [1]) (Logo: http://photos.prnewswire.com/prnh/20051018/CARDIUMLOGO [2]) The ASPIRE study is a 100-patient, randomized and controlled multi-center study being conducted at up to six leading cardiology centers in the Russian Federation. The study is designed to further evaluate the safety and effectiveness of Cardium's Generx DNA-based angiogenic product candidate, which has already been tested in clinical studies involving 650 patients at more than one hundred medical centers in the U.S., Europe and elsewhere. The therapeutic efficacy of Generx will be quantitatively assessed using rest and stress SPECT imaging (Single-Photon Emission Computed Tomography) to sensitively measure improvements in microvascular cardiac perfusion following a one-time, non-surgical, catheter-based administration of Generx. The Cedars-Sinai Medical Center Nuclear Cardiology Core Laboratory in Los Angeles, California, will serve as the central core lab for the ASPIRE study and will be responsible for the analysis of SPECT myocardial imaging data electronically transmitted from the Russian medical centers participating in the ASPIRE study. Advanced Biosciences Research, an affiliate of bioRASI which is a global clinical research organization, is Cardium's Russian sponsor and development partner and is responsible for the ASPIRE program management and regulatory compliance.

Generx is a disease-modifying regenerative medicine biologic that is being developed to offer a one-time, non-surgical option for the treatment of myocardial ischemia in patients with stable angina due to coronary artery disease, who might otherwise require surgical and mechanical interventions, such as coronary artery by-pass surgery or balloon angioplasty and stents. Similar to surgical/mechanical revascularization approaches, the goal of Cardium's Generx product candidate is to improve blood flow to the heart muscle - but to do so non-surgically, following a single administration from a standard cardiac infusion catheter. Additional information about Generx and the ASPIRE study is available in a presentation titled "Generx Angiogenic Therapy: Regenerative Medicine for Interventional Cardiology" at http://phx.corporate-ir.net/phoenix.zhtml?c=77949&p=irol-presentations [3], and at http://clinicaltrials.gov/ct2/show/NCT01550614?term=cardium&rank=1 [4].

The YouTube video, "Cardium Generx Cardio-Chant" is at http://www.youtube.com/watch?v=pjUndFhJkjM [5].

"The ASPIRE trial represents a major milestone for Cardium and is the fifth clinical study under Generx's clinical development program that when completed will have enrolled more than 750 patients at over 100 medical centers throughout the U.S., Canada, South America, Western Europe and Russia. With positive safety and efficacy data from this single registration study, a Generx clinical dossier would become eligible for submission for marketing and sales in the Russian Federation, and would also be expected to support submissions seeking approval for marketing and sales of Generx in certain other countries of the Commonwealth of Independent States, comprising former republics under the Soviet Union," stated Christopher J. Reinhard, Cardium's Chairman and Chief Executive Officer.

The ASPIRE study is also specifically designed to provide additional clinical evidence regarding the safety and effectiveness of Generx that would be useful for optimizing and broadening commercial development pathways in other industrialized countries such as Brazil, India, Europe and the United States.

Generx Clinical Development The ASPIRE study (A Randomized, Controlled, Parallel Group, Multi-center Study To Evaluate The Efficacy And Safety Of Ad5FGF-4 Using Adenosine SPECT Myocardial Perfusion Imaging In Patients With Stable Angina Pectoris) is expected to enroll approximately 100 men and women with myocardial ischemia due to coronary artery disease at up to six leading medical centers in Moscow. The primary efficacy endpoint of the study will be the improvement in reversible perfusion defect size as measured by SPECT myocardial perfusion imaging both at rest and under cardiovascular stress. The Russian Health Authority has assigned Generx the therapeutic drug trade name of CardionovoT for marketing and sales in Russia.

SPECT myocardial perfusion imaging can be used to quantitatively evaluate the therapeutic efficacy of Generx by measuring improved myocardial blood flow under stress; it is also a key prognostic indicator of future cardiovascular events. Generx may improve myocardial blood flow during stress - a change that is associated with the regenerative process of new collateral vessel formation in and around regions of ischemia. The Cedars-Sinai Core Laboratory was previously responsible for the data management, evaluation and interpretation of a successful Generx Phase 2 clinical study that also used SPECT myocardial perfusion imaging as the primary endpoint measure. Positive results from this Phase 2 clinical study (Grines et al., J Am Coll Cardiol 2003; 42:1339-47) showed that Generx could improve myocardial blood flow in the ischemic region of the hearts of patients following a single intracoronary infusion, as measured by SPECT imaging. The observed treatment effect (reduced reversible perfusion defect size) for patients receiving Generx was similar in magnitude to that reported in the literature for patients undergoing angioplasty/stent or surgical revascularization procedures.

Recent data from preclinical research conducted at Emory University provided further support for the apparent safety and effectiveness of Generx as a potential one-time non-surgical approach to the treatment of coronary heart disease. This important study demonstrated that induced transient ischemia, using a standard angioplasty balloon catheter, combined with intracoronary co-infusion of nitroglycerin, substantially enhanced adenovector-mediated gene expression in the

heart. Use of these newly applied gene transfer techniques increased the efficiency of gene transfer in preclinical studies by more than two orders of magnitude ($p<0.001$). These findings have been incorporated into the protocol for the ASPIRE study and the new data underscore the expected benefit of Cardium's improved adenovector administration methods. Use of combined non-surgical, percutaneous balloon catheter-based delivery with transiently-induced ischemia and nitroglycerin to enhance uptake is expected to lead to improved microvascular circulation in the heart. By increasing gene transfer efficiency, this modified delivery approach allows for maximizing targeted expression of FGF-4 protein within the ischemic heart of all treated patients, where the resulting angiogenesis or blood vessel growth can bring about improved blood flow. Traditional interventional approaches such as coronary artery bypass surgery (CABG) or angioplasty and stenting (PCI), not only require invasive and costly surgical procedures but they can only directly target selected vulnerable spots in larger vessels that are susceptible to treatment and reachable through mechanical intervention. The recent data, which were presented at the 2012 Annual Gene and Cell Therapy Forum entitled "ASPIRE Trial: A Phase 3 Pivotal Registration Trial Incorporating Preclinical and Clinical Lessons Learned in the Past Decade," can be viewed at http://www.cardiumthx.com/generx.html [6].

About Cardium Cardium is a health sciences and regenerative medicine company focused on the acquisition and strategic development of innovative bio-medical product opportunities and businesses with the potential to address significant unmet medical needs, and which also have definable pathways to commercialization, partnering and other economic monetizations. Cardium's current medical opportunities portfolio, which is focused on health sciences and regenerative medicine, includes the Tissue Repair Company, Cardium Biologics, and the Company's in-house MedPodium Health Sciences healthy lifestyle product platform. The Company's lead commercial product ExcellagenT topical gel for wound care management, has recently received FDA clearance for marketing and sale in the United States. Cardium's lead clinical development product candidate Generx@ is a DNA-based angiogenic biologic intended for the treatment of patients with myocardial ischemia due to coronary artery disease. In addition, consistent with its capital-efficient business model, Cardium continues to actively evaluate new technologies and business opportunities. In July 2009, Cardium completed the sale of its InnerCool Therapies medical device business to Royal Philips Electronics, the first asset monetization from the Company's biomedical investment portfolio. News from Cardium is located at www.cardiumthx.com [7].

Forward-Looking Statements Except for statements of historical fact, the matters discussed in this press release are forward looking and reflect numerous assumptions and involve a variety of risks and uncertainties, many of which are beyond our control and may cause actual results to differ materially from stated expectations. For example, there can be no assurance that enhancements in the uptake of adenovectors can be successfully applied to improve the uptake or therapeutic effects of Generx in human patients; that the ASPIRE clinical study will be successful or will lead to approval of Generx by the Russian Health Authority for marketing and sales in Russia or lead to approvals in other countries of the Commonwealth of Independent States; that results or trends observed in one clinical study or procedure will be reproduced in subsequent studies or procedures,

or that clinical studies even if successful will lead to product advancement or partnering; that improvements in the administration, formulation or use of Generx will be commercially practicable, or that Generx could be successfully advanced as a therapeutic in developing markets; that additional clinical evidence regarding the safety and effectiveness of Generx that might be obtained in Russia would be useful for optimizing and broadening commercial development pathways in other industrialized countries; that our products or product candidates will not be unfavorably compared to competitive products that may be regarded as safer, more effective, easier to use or less expensive; that FDA or other regulatory clearances or other certifications, or other commercialization efforts will be successful or will effectively enhance our businesses or their market value; that our products or product candidates will prove to be sufficiently safe and effective after introduction into a broader patient population; or that third parties on whom we depend will perform as anticipated.

Actual results may also differ substantially from those described in or contemplated by this press release due to risks and uncertainties that exist in our operations and business environment, including, without limitation, risks and uncertainties that are inherent in the development of complex biologics and in the conduct of human clinical trials, including the timing, costs and outcomes of such trials, our ability to obtain necessary funding, regulatory approvals and expected qualifications, our dependence upon proprietary technology, our history of operating losses and accumulated deficits, our reliance on collaborative relationships and critical personnel, and current and future competition, as well as other risks described from time to time in filings we make with the Securities and Exchange Commission. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date hereof.

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