

CV Therapeutics and Astellas Announce FDA Approval for Lexiscan(TM) (regadenoson) Injection

-First A2A Adenosine Receptor Agonist Approved for Use as Pharmacologic Stress Agent in Myocardial Perfusion Imaging-

PALO ALTO, Calif. and DEERFIELD, Ill., April 10 /PRNewswire-FirstCall/ -- CV Therapeutics, Inc. (Nasdaq: CVTX) and Astellas Pharma US, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved Lexiscan(TM) (regadenoson) injection, an A2A adenosine receptor agonist, for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging (MPI) -- a test that detects and characterizes coronary artery disease -- in patients unable to undergo adequate exercise stress.

Lexiscan is the first A2A adenosine receptor agonist shown to be safe and effective as a pharmacologic stress agent in MPI studies. Lexiscan is delivered as a rapid bolus (approximately 10 seconds) with no dose adjustment required for body weight. The A2A adenosine receptor is the adenosine receptor subtype responsible for coronary vasodilation.

MPI tests, commonly called cardiac stress tests, identify areas of poor blood flow in the heart to help detect and characterize coronary artery disease, the most common type of heart disease. Many patients exercise on a treadmill to generate the increase in coronary blood flow necessary to perform an MPI study. However, almost half of the patients undergoing the 7.5 to 9.3 million cardiac stress tests each year are unable to exercise adequately because of medical conditions. For these patients, a pharmacologic stress agent that temporarily increases blood flow through the coronary arteries is used to mimic the increase in coronary blood flow caused by exercise.

"Lexiscan represents the second novel chemical entity in cardiovascular medicine that CV Therapeutics has received approval for in just over two years," stated Louis G. Lange, M.D., Ph.D., chairman and chief executive officer of CV Therapeutics. "We are very excited to have Astellas -- the clear market leader in pharmacologic stress for MPI -- commercializing Lexiscan."

"We are extremely pleased that the FDA has approved Lexiscan, an exciting new option for diagnosing coronary artery disease in patients who cannot undergo an exercise stress test," said Yoshihiko Hatanaka, president and chief executive officer of Astellas Pharma US, Inc. "We are preparing to launch Lexiscan soon after this approval in order to provide clinicians with this important new option for patients who need pharmacologic stress agents for MPI studies."

Lexiscan Clinical Trials

In two identically designed Phase III clinical trials, Lexiscan met primary endpoints for scan agreement rates by showing with 95 percent confidence that MPI studies conducted with Lexiscan were similar to MPI studies conducted with Adenoscan(R) (adenosine injection).

Lexiscan was generally well-tolerated in both Phase III studies. The most common adverse events reported in patients who received Lexiscan were shortness of breath, headache, flushing, chest discomfort, dizziness and nausea.

About Lexiscan

Lexiscan is an A2A adenosine receptor agonist approved for use as a pharmacologic stress agent in radionuclide MPI studies in patients unable to undergo adequate exercise stress. Lexiscan was designed to produce coronary vasodilation and increase coronary blood flow by activation of the A2A adenosine receptor. Lexiscan is administered as a rapid bolus (approximately 10 seconds) with no dose adjustment required for body weight. Lexiscan should not be administered to patients with second- or third-degree AV block or sinus node dysfunction who do not have a functioning artificial pacemaker. Adenosine receptor agonists, including Lexiscan, induce arterial vasodilation and hypotension. The risk of serious hypotension may be higher in patients with cardiac or cerebrovascular insufficiency. Complete prescribing information for Lexiscan is available at <http://www.Lexiscan.com>.

Astellas Pharma US, Inc. / CV Therapeutics Inc. Collaboration

Under a license and collaboration agreement providing Astellas with exclusive North American rights to Lexiscan, CV Therapeutics manages the development program and Astellas is responsible for all commercial activities for Lexiscan in North America. Under the arrangement, Astellas paid CV Therapeutics a \$7 million milestone upon NDA submission and a \$12 million milestone upon FDA approval, and reimburses CV Therapeutics for 75 percent of development costs. CV Therapeutics will receive a royalty on product sales of Lexiscan, and may receive a royalty on another Astellas product. CV Therapeutics owns the rights for regadenoson outside of North America.

About Astellas Pharma US, Inc.

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 U.S., 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 Web site at <http://www.astellas.com/us>.

Astellas currently markets Adenoscan(R) (adenosine injection), the leading pharmacologic stress agent for MPI studies in the United States. Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. The most common side effects include flushing, chest discomfort and dyspnea. Less frequent side effects reported in patients administered Adenoscan include second and third degree AV block, fatal cardiac arrest, ventricular tachycardia and nonfatal myocardial infarction. For full prescribing information, please visit <http://www.adenoscan.com>.

About CV Therapeutics

CV Therapeutics, Inc., headquartered in Palo Alto, California, is a biopharmaceutical company primarily focused on applying molecular cardiology to the discovery, development and commercialization of novel, small molecule drugs for the treatment of cardiovascular diseases.

CV Therapeutics' approved products include Ranexa(R) (ranolazine extended-release tablets), indicated for the treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs, and Lexiscan(TM) (regadenoson) injection for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging. CV Therapeutics also has other clinical and preclinical drug development candidates and programs.

CV Therapeutics Conference Call

Company management will webcast a conference call on Friday, April 11, 2008 at 8:30 a.m. EDT, 5:30 a.m. PDT, on the company's website. To access the live webcast and corresponding slides, please log on to the Company's website at <http://www.cvt.com> and go to the Investor Information section. Alternatively, domestic callers may participate in the conference call by dialing (866) 524-6241, and international callers may participate in the conference call by dialing (706) 679-3061. Webcast and telephone replays of the conference call will be available approximately two hours after the completion of the call through Friday, April 18, 2008. Domestic callers can access the replay by dialing (800) 642-1687, and international callers can access the replay by dialing (706) 645-9291; the PIN access number is 42825384.

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including; the conduct and timing of studies; timing of regulatory submissions; timing of regulatory review and approval; commercialization of products; market acceptance of products; dependence on strategic collaborative partners; intellectual property protection and disputes; and other risks detailed from time to time in CV Therapeutics' SEC reports, including its Annual Report on Form 10-K for the year ended December 31, 2007. CV Therapeutics disclaims any intent or obligation to update these forward-looking statements.

SOURCE Astellas Pharma US, Inc.

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/CONTACT: CV Therapeutics Investors and Media, John Bluth of CV Therapeutics, Inc., +1-650-384-8850; or Astellas Media, Maribeth Landwehr of Astellas US LLC, +1-847-317-8988; or Katherine Williams, +1-312-397-6613, for Astellas Pharma US, Inc./

/First Call Analyst: /

/FCMN Contact: kwilliams@webershandwick.com /

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