



## News Release

Contact:  
Maribeth Landwehr  
Astellas US LLC  
(847) 317-8988

Katherine Williams  
For Astellas  
(312) 397-6613

For Immediate Release

**ASTELLAS LAUNCHES LEXISCAN™ (REGADENOSON) INJECTION FOR USE AS A  
PHARMACOLOGIC STRESS AGENT IN RADIONUCLIDE  
MYOCARDIAL PERFUSION IMAGING (MPI)**

**–First A<sub>2A</sub> Adenosine Receptor Agonist Approved for Use in Identifying  
Coronary Artery Disease–**

Deerfield, Ill., June 24, 2008 – Astellas Pharma US, Inc. today announced the commercial availability of Lexiscan™ (regadenoson) injection, an A<sub>2A</sub> adenosine receptor agonist, for use as a pharmacologic stress agent in radionuclide MPI – a test that detects and characterizes coronary artery disease – in patients unable to undergo adequate exercise stress. Lexiscan, co-developed with CV Therapeutics (NASDAQ: CVTX), is the first A<sub>2A</sub> adenosine receptor agonist shown to be safe and effective as a pharmacologic stress agent in MPI studies. The A<sub>2A</sub> adenosine receptor subtype is primarily responsible for coronary vasodilation.

“Our clinical experience shows that an increasing number of patients are requiring pharmacologic stress agents for MPI studies,” said Gregory Thomas, M.D., Clinical Associate Professor of Medicine and Director of Nuclear Cardiology Education at the University of California at Irvine School of Medicine. “Lexiscan will be an important option in helping to ensure proper diagnosis of coronary artery disease in these patients.”

MPI tests, commonly called cardiac stress tests, identify areas of poor blood flow in the heart to determine the extent of coronary artery disease, a condition that affects 16 million Americans and is responsible for more than 450,000 deaths annually in the United States. Many patients exercise on a treadmill to generate the increase in coronary blood flow necessary to perform an

MPI study. However, almost half of patients undergoing 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. About 7.5 to 9.3 million MPI studies were performed last year in the U.S.

### **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<sup>®</sup> (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, angina or ST-segment depression, dizziness and nausea.

### **About Lexiscan**

Lexiscan is an A<sub>2A</sub> 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 A<sub>2A</sub> adenosine receptor. Lexiscan is administered as a rapid intravenous injection (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. Adenosine receptor agonists may induce bronchoconstriction and respiratory compromise in patients with COPD or asthma. Complete prescribing information for Lexiscan is available at [www.Lexiscan.com](http://www.Lexiscan.com).

### **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 [www.astellas.com/us](http://www.astellas.com/us).

Astellas currently markets Adenoscan<sup>®</sup> (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 [www.adenoscan.com](http://www.adenoscan.com).

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