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Contact: Jenny Keeney
Astellas US LLC
(847) 317-5405

**LEXISCAN® (REGADENOSON) INJECTION STUDY IN SUBJECTS WITH
ASTHMA OR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PRESENTED AS
LATE-BREAKER AT AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY 2010**

Phase IV Data Meets Primary Endpoint

PHILADELPHIA, PA, September 25, 2010 – Today Astellas Pharma US, Inc., (“Astellas”) announced results of a Phase IV study showing Lexiscan® (regadenoson) Injection was comparable to placebo in causing a >15% decrease in forced expiratory volume in one second (FEV₁) in subjects with asthma or chronic obstructive pulmonary disease (COPD) who are likely candidates for myocardial perfusion imaging (MPI) studies¹. Results were presented during an oral presentation today at the 15th Annual Scientific Sessions of the American Society of Nuclear Cardiology (ASNC) in Philadelphia, Pennsylvania during a session highlighting late-breaker data.

Statistically, regadenoson was found to be not significantly different from placebo in causing a >15% decrease in FEV₁ in patients with asthma (p = 0.1451) or COPD (p = 0.5790). Additionally, the change in FEV₁ was not affected by baseline disease severity for either the asthma or the COPD subject groups.

Researchers evaluated 999 adult male and female patients (532 asthma and 467 COPD) 18 years of age and older in a multicenter, randomized, double-blind, placebo-controlled study to determine the safety and tolerability of regadenoson in subjects with asthma (FEV₁ ≥60% predicted) or stable COPD (FEV₁/FVC <0.70). The subjects had a diagnosis of CAD or risk factors for CAD as determined by a current medical diagnosis of at least two of the following conditions: Type 2 diabetes, hypertension, hypercholesterolemia, current or history of cigarette smoking (minimum 10 pack-years exposure) or obesity Body Mass Index (BMI > 30). A 2:1 randomization to receive a single 10-second IV injection of Lexiscan 0.4 mg (in 5 mL) or placebo was used.

Treatment-emergent adverse events were similar in frequency and severity to those observed in previous studies of regadenoson. Two regadenoson subjects in the COPD group received aminophylline for treatment of adverse events.

About Myocardial Perfusion Imaging

MPI studies, commonly called cardiac stress tests, identify areas of poor blood flow in the heart to determine the extent of coronary artery disease (CAD)², a condition that affects about 17.5 million³ Americans each year. Though many patients exercise on a treadmill to generate the increase in coronary blood flow necessary to perform an MPI study, almost half who undergo cardiac stress tests are unable to exercise adequately because of medical conditions⁴. 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 achieved by exercise.

About Lexiscan

Lexiscan is an A_{2A} adenosine receptor agonist approved for use as a pharmacologic stress agent in radionuclide MPI 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_{2A} adenosine receptor. Lexiscan is administered as a standard dose intravenous injection (approximately 10 seconds).

Important Safety Information

Do not administer Lexiscan to patients with second- or third-degree AV block or sinus node dysfunction unless these patients have a functioning artificial pacemaker.

Fatal cardiac arrest, life-threatening ventricular arrhythmias, and myocardial infarction may result from the ischemia induced by pharmacologic stress agents. Cardiac resuscitation equipment and trained staff should be available before administering Lexiscan.

Adenosine receptor agonists, including Lexiscan, can depress the SA and AV nodes and may cause first-, second-, or third-degree AV block, or sinus bradycardia requiring intervention. In postmarketing experience, heart block (including third degree), and asystole within minutes of Lexiscan administration have occurred.

Adenosine receptor agonists, including Lexiscan, induce arterial vasodilation and hypotension. In postmarketing experience, syncope, transient ischemic attacks, and seizures have been observed. In clinical trials, decreased systolic blood pressure (>35 mm Hg) was observed in 7% of patients and decreased diastolic blood pressure (>25 mm Hg) was observed in 4% of patients within 45 minutes of Lexiscan administration. The risk of serious hypotension may be higher in patients with autonomic dysfunction, hypovolemia, left main coronary artery stenosis, stenotic valvular heart disease, pericarditis or pericardial effusions, or stenotic carotid artery disease with cerebrovascular insufficiency.

Adenosine receptor agonists, including Lexiscan, may result in clinically significant increases in blood pressure in some patients. When it occurred in clinical trials, increased blood pressure was observed within minutes of Lexiscan administration, and in most cases, resolved within 10 to 15 minutes. In some cases, blood pressure increases were observed 45 minutes following Lexiscan administration. In postmarketing experience, cases of potentially clinically significant hypertension have been reported, particularly in patients with underlying hypertension and when low-level exercise was included in the MPI.

Adenosine receptor agonists, including Lexiscan, may cause bronchoconstriction and respiratory compromise. For patients with known or suspected bronchoconstrictive disease, chronic obstructive pulmonary disease (COPD), or asthma, appropriate bronchodilator therapy and resuscitative measures should be available prior to Lexiscan administration.

Lexiscan overdosage may result in serious reactions. Aminophylline was used as a reversal agent in 3% of patients.

The most common adverse reactions ($\geq 5\%$) to Lexiscan are dyspnea, headache, flushing, chest discomfort, angina pectoris or ST-segment depression, dizziness, chest pain, nausea, abdominal discomfort, dysgeusia, and feeling hot. Most adverse reactions began soon after dosing, and generally resolved within approximately 15 minutes, except for headache, which resolved in most patients within 30 minutes.

In postmarketing experience, abdominal pain in association with nausea, vomiting, or myalgias, and diarrhea, fecal incontinence, musculoskeletal pain, and tremor have occurred.

Complete prescribing information for Lexiscan is available at www.astellas.us/docs/lexiscan.pdf. For more information on Lexiscan, please visit www.lexiscan.com.

About Astellas

The Astellas culture and brand is committed to building community, helping others, encouraging integrity and inspiring people to make a difference, today, tomorrow and every day. 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 United States, Astellas markets products in the areas of Anti-Infectives, Cardiology, Dermatology, Neuroscience, Transplant, and Urology. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.us or follow us on Twitter at www.Twitter.com/AstellasUS.

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References

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2. National Heart Lung and Blood Institute. What to expect during stress testing. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/stress/stress_during.html. Accessed on September 7, 2010.
3. Lloyd-Jones D, et al. Heart Disease and Stroke Statistics 2010 Update: A Report from the American Heart Association.
4. AMR data on file.

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