Summary of Results for Laypersons

Astellas is grateful to the patients who took part in this clinical study. Thank you.

What was the Study Called?

A Phase 2, Open-Label, Randomized, Cross-Over Study of Regadenoson in Subjects Undergoing Stress Myocardial Perfusion Imaging by Multidetector Computed Tomography (MDCT) and Single Photon Emission Computed Tomography (SPECT)

Why was this Study Needed?

Coronary artery disease (or CAD for short) is the most common type of heart disease. It is associated with areas of decreased blood flow and oxygen in the heart muscle. Those areas cause chest pain and discomfort ("angina"). If not treated, these areas can result in a heart attack. They can be detected by comparing rest and stress images of the heart muscle. Stress occurs when the heart has to work harder to pump blood throughout the body. Stress can be brought on by exercise, such as walking on a treadmill. For patients who are unable to exercise, stress can be brought on by a drug such as regadenoson (also known as Lexiscan® or CVT3146). Regadenoson is injected through a small needle placed in a vein in the arm.

To obtain heart muscle images, a nuclear stress test is done. A small amount of radioactive dye is injected into a vein. The dye travels through the blood vessels to the heart muscle. An imaging scan, such as a single photon emission computed tomography (or SPECT for short) scan, detects the dye's radiation. It uses that to create images of the heart muscle. One set of images is created while the patient is at rest. Another set of images is created while the patient is undergoing stress.

A coronary computed tomographic angiography (or CCTA for short) scan detects narrowing in the arteries of the heart. But it cannot tell if such narrowing leads to decreased oxygen to the heart muscle. A CCTA scan can be combined with a stress test and imaging that shows the blood flow through the heart muscle. This is called a computed tomography perfusion (or CTP for short) scan. If the scanner has multiple detectors, it is called an MDCT perfusion scan. Stress MDCT perfusion detects areas of decreased blood flow and oxygen in the heart muscle. There was a need to study if stress MDCT perfusion can do that as accurately as stress SPECT.

This study was conducted in patients with angina. The study looked at areas of decreased blood flow and oxygen in the heart muscle. The study compared stress MDCT perfusion scans to stress SPECT scans for spotting those areas. Regadenoson was used to bring on the stress. It was also important to find out what unwanted effects these patients had from receiving regadenoson.

The study started in April 2011 and ended in July 2012. When the study ended, the sponsor of this study (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was an "open-label" study. This means that each patient and the study doctors knew when that patient received the drug (regadenoson). And this means that each patient and the study doctors knew which stress scan (MDCT perfusion or SPECT) that patient had done.

This study included adult women and men who had angina. The women were aged 50 years or older. The men were aged 45 years or older. They had already been diagnosed with CAD or their doctor suspected they had CAD. Or they had stable symptoms and had a heart procedure scheduled for which further imaging might help. They were referred for a heart muscle imaging or scan. They had no problems with heart rate speed or rhythm.

During the study, the study doctor did a check-up of the patients at several study visits. At the first visit, they were checked to see if they could be in the study. Patients who could be in the study were picked for 1 of 2 imaging sequence groups by chance alone.

- Group 1—SPECT followed by MDCT perfusion:
  First day: The patients had a SPECT scan at rest and then a stress SPECT scan.
  One to 3 days later: They had a stress MDCT perfusion scan. At least 30 minutes thereafter, they had a CCTA/CTP scan at rest.
- Group 2—MDCT perfusion followed by SPECT:
  First day: The patients had a stress MDCT perfusion scan. At least 30 minutes thereafter, they had a CCTA/CTP scan at rest.
  One to 3 days later: They had a SPECT scan at rest and then a stress SPECT scan.

Patients received regadenoson (0.4 mg) before each stress SPECT and stress MDCT perfusion scan.

This study took place at 11 clinics in the US. 124 patients were in the study. Out of these patients, 118 patients received at least 1 dose of the drug regadenoson.

	Number of Patients
Age Group Aged between 45 and 85 years	 118
Sex Men Women	 85 33

What Were the Study Results?

This study in patients with angina compared stress MDCT perfusion scans to stress SPECT scans for spotting areas of decreased blood flow and oxygen in the heart muscle. Regadenoson was used to bring on the stress.

110 patients had both stress MDCT perfusion and stress SPECT scans done. This study looked at areas of decreased blood flow and oxygen in the heart muscle. It showed that stress MDCT perfusion spotted 25 patients with those areas. And stress SPECT spotted 10 patients with those areas. Nine of the 10 patients detected by stress SPECT were detected by stress MDCT perfusion as well.

This study showed that when stress was brought on by regadenoson, stress MDCT perfusion was not worse than stress SPECT in spotting areas of decreased blood flow and oxygen in the heart muscle.

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

The table below shows the most common adverse reactions experienced by patients who received at least 1 dose of the drug (regadenoson) in this study.

Adverse Reaction	**Regadenoson (out of 118 patients)**
Any adverse reaction	79 (66.9%)
Sudden reddening of the face and/or neck	40 (33.9%)
Headache or head pain	24 (20.3%)
Chest pain related to a heart problem	17 (14.4%)
Shortness of breath	16 (13.6%)
Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)	15 (12.7%)
Chest pain or discomfort due to decreased blood flow and oxygen to the heart muscle	11 (9.3%)
Nausea or the urge to vomit	11 (9.3%)
Upper belly pain	5 (4.2%)
Pain in jaw	3 (2.5%)
Stomach discomfort	3 (2.5%)
Stomach pain or belly ache	3 (2.5%)
Taste changes	3 (2.5%)

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care.

None of the patients experienced serious adverse reactions in this study.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study and reflects the information available as of May 2013. You can find this summary and more information about this study online at http://www.astellasclinicalstudyresults.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

Sponsor contact details:

Astellas Pharma Global Development, Inc.
1 Astellas Way
Northbrook, IL 60062
USA