Summary of Results for Laypersons

What was the Study Called?

A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, and Dose-ranging Study of YM443 in Subjects with Functional Dyspepsia

Why was this Study Needed?

Functional dyspepsia (FD) is a medical term for a condition which can cause upper stomach pain or discomfort. Additional symptoms may include: bloating, a feeling of fullness and heartburn. FD is a very common condition with a major impact on quality of life and high socio-economic and healthcare costs. Acotiamide (previously called YM443) is a prescription medicine used to treat patients with FD.

This study was done to help understand how patients respond to different amounts of acotiamide in order to better design other studies. Also, it was important to find out what unwanted effects might occur.

The main question this study helped answer was which dose of acotiamide (300, 600, or 900 mg) three times daily is better when compared to a placebo in treating patients with FD.

This phase 2 study was started at 79 clinics in the United States; 60 of which enrolled patients. The study took place between March 2004 and March 2006. When the study ended the sponsor (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 a "blinded" study. In this study, the patients and the researchers did not know who took which of the treatments (acotiamide or placebo). Patients were picked for each treatment by chance alone. "A placebo" is a dummy treatment such as a tablet or capsule that looks like a medicine, but does not contain any medicine at all. Using a placebo helps make study results fair and unbiased, because researchers and patients cannot tell who is taking a placebo, and who is taking the study medicine.

Both men and women between the ages of 18 to 75 years with symptoms of FD took part in the study.

The treatment period for this study was 12 weeks. Before the treatment period, all patients entered a 2-week proton pump inhibitor (PPI) "run-in" period. A PPI is a medicine that works to reduce the amount of stomach acid produced in the lining of the stomach. Patients who did not respond to the PPI treatment entered the 2-week PPI washout baseline evaluation period. A "washout period" is when the patient does not take any medicine to allow the medicine left in their body to be eliminated or "washed-out." After the washout and baseline evaluation period, 413 patients received at least one dose of either placebo (103 patients), acotiamide 300 mg three times daily (102 patients), acotiamide 600 mg three times daily (105 patients), or acotiamide 900 mg three times daily (103 patients).

The 413 patients are listed below:

	Number of Patients
Age Group Aged 18 years and older	 413
Men Women	125 288
EU Countries	0
Outside EU	413

What Were the Study Results?

Results from the study showed that at week 12 there were no significant differences between acotiamide and placebo in relief of FD symptoms.

Based on the safety examination performed in this study, acotiamide was safe and generally well tolerated.

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 at least 4 patients in any treatment group while taking part in this study.

	Number of Patients			
Adverse Reaction	**Placebo (out of 103)**	**Acotiamide 300 mg (out of 102)**	**Acotiamide 600 mg (out of 105)**	**Acotiamide 900 mg (out of 103)**
Nausea or the urge to vomit	11	10	5	7
Headache or head pain	6	2	8	4
Dizziness or sensation of lightheadedness, unsteadiness or giddiness	6	2	2	2
Upper belly pain	3	3	6	2
Constipation	4	4	3	4
Diarrhea	4	6	7	3

An adverse reaction is considered "serious" when it is life threatening, causes lasting problems, or needs hospital care. One patient in the acotiamide 900 mg group had a serious adverse reaction.

There were no deaths in the study.

Where Can I Learn More About This Study?

This summary of the clinical study results is available 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. If you have questions about acotiamide, please discuss these with your doctor.

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