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 1b, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Sequential Dose Study of the Safety and Tolerability of ASP0777 in Subjects with Alzheimer's Disease on Donepezil.

Why was this Study Needed?

Dementia is the name for a group of symptoms that cause memory, thinking and social abilities to decline. This decline is severe. It makes everyday activities hard to do for patients with dementia. Alzheimer's disease is the most common form of dementia. Better medicines to treat Alzheimer's are needed. ASP0777 is an experimental medicine taken by mouth (orally). It may improve Alzheimer's symptoms.

This study was conducted in patients with Alzheimer's who were taking donepezil (a common medicine for Alzheimer's). In this study, patients also took ASP0777 or placebo. (The section below describes what placebo tablets are.) This study looked at how safe it was for patients to take ASP0777. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in June 2011 and ended in November 2011. 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 a "double-blinded" study. That means that the patients and the study doctors did not know who took which of the study medicines (ASP0777 or placebo). A "placebo" is a dummy treatment such as a tablet or capsule that looks like a medicine, but does not have any medicine in it. Using a placebo helps make study results fair and unbiased, because study doctors and patients cannot tell who is taking a placebo, and who is taking the test medicine.

This study included men and women who were at least 50 years old and had Alzheimer's. Their Alzheimer's symptoms were mild to moderate. They had been taking prescribed donepezil for at least 3 months before the study started. And they had taken the same dose of donezepil for at least the past 6 weeks.

The study doctor did a check-up of the patients at several study visits. At the first visit, patients were checked to see if they could be in the study. Patients who could be in the study were treated by group (group 1 or 2).

Patients were picked for a treatment (ASP0777 or placebo) by chance alone. More patients were picked for ASP0777 than for placebo. All patients continued to take their prescribed dose of donezepil during the study.

Patients in group 1 took 10 mg (1 tablet) of ASP0777 or placebo (1 tablet) once a day for 6 weeks.

After 6 weeks, the study doctor found no safety issues in the patients in group 1. Next, patients in group 2 took 1 of 3 treatments.

- ASP0777 10/20 mg: Patients took 10 mg (1 tablet) of ASP0777 and placebo (1 tablet) once a day for 1 week. Thereafter, they took 20 mg (2 tablets) of ASP0777 once a day for 5 weeks.
- ASP0777 20 mg: Patients took 20 mg (2 tablets) of ASP0777 once a day for 6 weeks.
- Placebo: Patients took placebo (2 tablets) once a day for 6 weeks.

This study took place at 2 clinics in the United States. 60 patients were in the study and took at least 1 dose of study medicine.

	Number of Patients
Age Group Aged between 51 and 83 years	 60
Sex Men Women	 16 44

What Were the Study Results?

This study looked at how safe it was for patients with Alzheimer's disease to take ASP0777. The study looked at the medical problems (called "adverse events") patients had.

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.

The study showed that it was safe for patients with Alzheimer's to take ASP0777 for 6 weeks.

After 6 weeks of treatment with 10, 20 or 10/20 mg of ASP0777, the patients had similar adverse events. Their adverse events were similar to patients who took placebo for 6 weeks. The table below shows the most common adverse events experienced by patients who took at least 1 dose of study medicine in this study. The intensity of most adverse events was mild to moderate.

Adverse Event	Placebo (out of 15 patients)	ASP0777		
		10 mg (out of 15 patients)	20 mg (out of 15 patients)	10/20 mg (out of 15 patients)
Any adverse event	9 (60.0%)	8 (53.3%)	10 (66.7%)	10 (66.7%)
Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)	4 (26.7%)	2 (13.3%)	6 (40.0%)	5 (33.3%)
Headache or head pain	4 (26.7%)	4 (26.7%)	3 (20.0%)	3 (20.0%)
Sleepiness, the state of feeling drowsy, ready to fall asleep	1 (6.7%)	3 (20.0%)	2 (13.3%)	1 (6.7%)
Nausea or the urge to vomit	2 (13.3%)	1 (6.7%)	3 (20.0%)	1 (6.7%)
Back pain	1 (6.7%)	0	1 (6.7%)	0
Constipation	1 (6.7%)	1 (6.7%)	0	0
Vomiting	1 (6.7%)	1 (6.7%)	1 (6.7%)	0
Diarrhea	0	1 (6.7%)	1 (6.7%)	0
Feeling of spinning or whirling	1 (6.7%)	0	1 (6.7%)	0
Feelings of sadness, worthlessness, thoughts of suicide or death (depression)	1 (6.7%)	0	1 (6.7%)	0
Fatigue or tiredness	0	0	1 (6.7%)	1 (6.7%)
Sudden and involuntary contraction of 1 or more muscles	1 (6.7%)	1 (6.7%)	0	1 (6.7%)

What Adverse Reactions did Patients Have?

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.

In this study, all adverse events of dizziness (or sensation of lightheadedness, unsteadiness, or giddiness) were adverse reactions. Most adverse events of headache or head pain were adverse reactions.

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

None of the patients experienced a serious adverse reaction 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 August 2012. 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.

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