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 2a, Randomized, Double-Blind, Placebo-Controlled, Sequential Group, Multiple-Dose Escalation Study to Evaluate the Efficacy and Safety of ASP015K in Subjects with Moderate to Severe Plaque Psoriasis

Why was this Study Needed?

Psoriasis is thought to be the result of a problem with defensive white blood cells (T-cells) in the immune system. The immune system is part of the body that fights foreign objects or infections. The T-cells normally attack germs in the body. But patients with psoriasis have abnormal T-cells, which attack healthy skin cells. The abnormal T-cells increase production of healthy skin cells and more T-cells and other white blood cells (neutrophils). This results in the plaques of plaque psoriasis. Plaques are thick, red patches of skin with flaky, silver-white scales. There are few medicines to treat psoriasis symptoms that patients can take by mouth (orally). Therefore, there was a need to study a new oral treatment for plaque psoriasis. ASP015K (also known as peficitinib) is an experimental oral medicine for plaque psoriasis.

This study was conducted in patients who had moderate to severe plaque psoriasis. These patients took placebo or ASP015K for 6 weeks. (The section below describes what placebo tablets are.) This study measured if patients' symptoms improved over that time. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in March 2010 and ended in July 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 (ASP015K 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 adult women and men aged 18 years or older. These patients had moderate to severe plaque psoriasis for at least 6 months before the study started.

During the study, 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. All patients who could be in the study were picked for 1 of 2 treatments (ASP015K or placebo) by chance alone. Three times as many patients were picked for ASP015K than for placebo.

- ASP015K: Patients took the same dose of ASP015K tablets each day for 6 weeks. Their dose was 20, 50, 120 or 200 mg per day. Of the patients who took 50 mg per day, some took this over 2 doses (25 mg twice a day). Others took it as 1 dose (50 mg once a day).
- Placebo: Patients took placebo tablets each day for 6 weeks.

This study took place at 11 clinics in the US. 124 patients were in the study and took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	113
Aged 65 years or older	11
Sex	
Men	97
Women	27

What Were the Study Results?

Patients with moderate to severe plaque psoriasis took study medicine (placebo or ASP015K) for 6 weeks in this study. The study measured the Psoriasis Area and Severity Index (PASI) score. A decrease in PASI score after 6 weeks meant that plaque psoriasis symptoms had improved.

The study results showed that after 6 weeks, the average decrease in PASI score was 4.24 in patients who took placebo. And it was between 6.41 and 11.92 in patients who took ASP015K. This means that plaque psoriasis symptoms improved more with ASP015K than with placebo. A statistical test showed that the difference was not likely to be due to chance.

		Total Dose of ASP015K (taken over 2 doses) per Day				
Study Results After Treatment for 6 Weeks	**Placebo (29 patients)**	**20 mg (19 patients)**	**50 mg (21 patients)**	**50 mg (*taken as 1 dose*) (19 patients)**	**120 mg (19 patients)**	**200 mg (17 patients)**
Average decrease in PASI score	4.24	6.41	6.47	6.59	8.26	11.92

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 took at least 1 dose of study medicine in this study.

Most Common Adverse Reaction	Placebo (out of 29 patients)	Total Dose of ASP015K (taken over 2 doses) per Day				
		20 mg (out of 19 patients)	50 mg (out of 21 patients)	50 mg (*taken as 1 dose*) (out of 19 patients)	120 mg (out of 19 patients)	200 mg (out of 17 patients)
Any adverse reaction	7 (24.1%)	1 (5.3%)	5 (23.8%)	3 (15.8%)	4 (21.1%)	7 (41.2%)
Excess passing of gas	1 (3.4%)	0	1 (4.8%)	1 (5.3%)	1 (5.3%)	1 (5.9%)
Heartburn	1 (3.4%)	0	1 (4.8%)	1 (5.3%)	0	0
Acne	0	0	0	0	0	3 (17.6%)
Infection of the upper respiratory tract (nose, sinuses, throat, windpipe, and voice box)	0	0	0	1 (5.3%)	1 (5.3%)	1 (5.9%)

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 February 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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