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, Open-Label, Single Sequence, Drug Interaction Study to Evaluate the Pharmacokinetics of ASP015K and Methotrexate in Subjects with Rheumatoid Arthritis

Why was this Study Needed?

The immune system is part of the body that fights foreign objects or infections. Patients with rheumatoid arthritis (or RA for short) have a faulty immune system that attacks the body's own tissues. As a result, these patients have inflammation (swelling and redness) and damage in joints (arthritis). Methotrexate is an oral prescription medicine (taken by mouth) that slows down the progress of joint damage in RA patients. It may cause unwanted effects or may not work well enough in some patients. ASP015K (also known as peficitinib) is a new oral prescription medicine for RA in Japan. There was no information on what effect ASP015K may have on methotrexate when the 2 medicines are taken together. Therefore, there was a need to study that.

This study was conducted in patients with RA. This study looked at the effect of ASP015K on the total level of methotrexate in the patient's blood over time. The study also looked at the effect of ASP015K on the peak level of methotrexate in the blood. It measured the total and peak levels of methotrexate after patients took methotrexate alone. And it compared those levels to the levels after patients took methotrexate together with ASP015K. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in January 2010 and ended in March 2010. 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 all patients and the study doctors knew which study medicines the patients took (ASP015K and methotrexate).

This study included women and men aged between 18 and 65 years. The patients had RA for at least 6 months before the study started. They had been taking the same weekly dose of methotrexate (15 to 25 mg) for at least 4 weeks 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 took the following study medicines from days 1 through 9:

- They took methotrexate tablets once a day (15 to 25 mg) on days 1 and 8.
- They took ASP015K tablets 100 mg twice a day (total of 200 mg) on days 3 through 8. On day 9, patients took ASP015K 100 mg only in the morning (total of 100 mg).

This study took place at 1 clinic in the United States. 15 patients were in the study and took at least 1 dose of study medicine.

	Number of Patients
Age Group Aged 35 to 64 years	 15
Sex Men Women	 4 11

What Were the Study Results?

This study in patients with RA looked at the effect of ASP015K on methotrexate when the 2 study medicines were taken together. It measured the total and peak levels of methotrexate after patients took methotrexate alone. And it compared those levels to the levels after patients took methotrexate together with ASP015K.

ASP015K had no effect on the level of methotrexate in the blood. Total levels in the blood over time were similar after patients took methotrexate alone or together with ASP015K. The same was true for peak levels in the blood.

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 adverse reactions experienced by patients who took at least 1 dose of study medicines in this study.

Adverse Reaction	Methotrexate and/or ASP015K (out of 15 patients)
Any adverse reaction	6 (40.0%)
Excess passing of gas	3 (20.0%)
Belching or burping	1 (6.7%)
Diarrhea	1 (6.7%)
Excess amount of gastric juice flowing back (refluxes) into the esophagus (gullet or the tube that goes from mouth to stomach through which food passes), causing heartburn and possibly damaging the esophagus	1 (6.7%)
Nausea or the urge to vomit	1 (6.7%)
Ongoing or recurrent burning in the mouth without an obvious cause (burning mouth syndrome)	1 (6.7%)
Swelling or feeling of fullness and tightness in the abdomen (belly)	1 (6.7%)

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 November 2010. 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
1 Astellas Way
Northbrook, IL 60062
USA