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, Noncomparative, Multicenter Extension Study to Evaluate the Long-term Safety and Efficacy of ASP015K in Subjects Previously Enrolled in a Phase 2 ASP015K Rheumatoid Arthritis Study

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. At the start of this study, there was no information about how ASP015K works over the long term. Therefore, there was a need to study that.

This study was conducted in patients with moderate to severe RA. These patients had taken ASP015K for 3 months in an earlier study and continued taking it in this study. This study looked at how safe it was for patients to take ASP015K for up to 2 years. It was also important to find out what unwanted effects these patients had from ASP015K.

The study started in September 2012 and ended in March 2016. 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 medicine the patients took (ASP015K).

This study included adult women and men aged 18 years or older. They had moderate to severe RA. The patients had RA for at least 6 months before they took part in 1 of 2 earlier studies of ASP015K. In the earlier studies, they took ASP015K or placebo tablets once a day for 3 months. 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. In 1 of the earlier studies, the patients also took their prescribed weekly dose of methotrexate.

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 took ASP015K tablets (100 mg) once a day. They took study medicine for up to 2 years.

This study took place at 51 clinics in several countries. 611 patients were in the study and took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	508
Aged 65 years or older	103
Sex	
Men	107
Women	504
Clinic Location	
European Union Countries (*at the time of the study*)	258
Belgium	8
Bulgaria	20
Czech Republic	52
Hungary	40
Poland	138
Outside European Union	353
Colombia	23
Mexico	74
The US	256

What Were the Study Results?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied study doctors 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.

This study looked at how safe it was for patients with RA to take ASP015K for up to 2 years. The table below shows the most common adverse events experienced by patients who took at least 1 dose of ASP015K in this study.

Most Common Adverse Event	ASP015K 100mg (out of 611 patients)
Any adverse event	463 (75.8%)
Infection of the upper respiratory tract (nose, sinuses, throat, wind pipe and voice box)	77 (12.6%)
Urinary tract infection	53 (8.7%)
Common cold	42 (6.9%)
Inflammation of the airways of the lungs	42 (6.9%)
Increased blood level of cholesterol	38 (6.2%)
Headache or head pain	33 (5.4%)
Increased blood level of enzyme (creatine phosphokinase) from muscle	29 (4.7%)
Urinary tract infection caused by bacteria	28 (4.6%)
Worsening of a disease that mainly affects the joints (rheumatoid arthritis)	28 (4.6%)
Diarrhea	27 (4.4%)
Flu	27 (4.4%)
High blood pressure	26 (4.3%)
Nausea or the urge to vomit	25 (4.1%)

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.

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	ASP015K 100mg (out of 611 patients)
Any adverse reaction	222 (36.3%)
Infection of the upper respiratory tract (nose, sinuses, throat, wind pipe and voice box)	41 (6.7%)
Increased blood level of cholesterol	26 (4.3%)
Urinary tract infection caused by bacteria	21 (3.4%)
Increased blood level of enzyme (creatine phosphokinase) from muscle	19 (3.1%)
Urinary tract infection	17 (2.8%)
Headache or head pain	16 (2.6%)

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

24 patients (3.9%, or 24 out of 611 patients) experienced serious adverse reactions in this study.

Two patients died during the study. Neither patient died because of ASP015K.

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 2016. 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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