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 1 Open-label, Single-sequence, Drug Interaction Study to Evaluate the Pharmacokinetics of ASP1707 and Methotrexate in Patients 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 (RA) 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 for RA (taken by mouth) that slows down the progress of joint damage in patients. It reduces inflammation but may cause unwanted effects or may not work well in some patients.

Study drug ASP1707 is an experimental medicine that is taken by mouth. It blocks or dampens the effect of Gonadotropin releasing hormone (GnRH). A medicine similar to ASP1707 was able to reduce inflammation. At the start of this study, there was no information about the effect of taking ASP1707 together with methotrexate. Therefore, there was a need to study ASP1707 in RA patients who had been taking methotrexate.

This study looked at the effect of ASP1707 on the total level of methotrexate in the patient's blood over time. The study also looked at the effect of ASP1707 on the peak level of methotrexate in the blood. It measured the total and peak levels after patients took methotrexate alone. And it compared those levels to the levels after patients took methotrexate together with ASP1707.

It was also important to find out what unwanted effects these patients had from receiving ASP1707 and methotrexate together.

The study started in July 2016 and ended in August 2016. When the study ended, 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 patients and the study doctors knew the patients took ASP1707 and methotrexate.

This study included women and men aged between 18 and 65 years old. Their doctor had determined that they had RA. The patients had RA for at least 6 months before the study started.

The patients had been taking the same weekly dose of methotrexate (10 to 25 mg) for at least 4 weeks before the study started. They had the ability to carry on all normal activities without problems. Or they were able to conduct normal activities despite pain or limited use of 1 or more joints.

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. Patients who could be in the study took the study medicines in the following order: On day 1, patients took methotrexate tablets (10 to 25 mg). On days 3 through 8, patients took ASP1707 tablets (30 mg) twice a day. On day 8, patients took methotrexate tablets (10 to 25 mg). On day 9, patients took ASP1707 tablets (30 mg) in the morning.

This study took place at 1 clinic in Europe, Republic of Moldova. 10 patients were in the study and received at least 1 dose of study medicine.

	Number of Patients
Age Group Aged 40 to 64 years	 10
Sex Men Women	 2 8

What Were the Study Results?

This study looked at the effect of ASP1707 on the total and peak levels of methotrexate in the patient's blood over time.

A small increase in the overall amount of methotrexate in the blood was seen when ASP1707 and methotrexate were taken together as compared to when methotrexate was taken alone.

In addition, treatment with both ASP1707 and methotrexate resulted in a slightly higher peak level of methotrexate in the blood as compared to the peak level when methotrexate was taken alone.

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.

None of the patients experienced an adverse reaction.

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 March 2017. 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