Plain Language Summary of Study Results

Astellas is grateful to the people who took part in this clinical study. Thank you.

What was the study called?

A Study of a Vaccine, ASP0113, to Prevent Infections of Cytomegalovirus (CMV) in People Who have Received a Kidney Transplant

Why was the study needed?

Human cytomegalovirus (or CMV for short) is a type of herpes virus. The immune system is part of the body that fights foreign objects or infections. People with organ transplants have to take medicines that reduce the strength of their immune system. Otherwise, their immune system would reject the organ transplants as foreign objects. Because their immune system is reduced in strength, they can get very sick from a CMV infection. Vaccines can help the immune system protect against an infection. They contain pieces of a germ (bacteria or virus) and mimic a natural infection. The body responds by creating antibodies to fight the infection. When the antibodies bind to the germ, it can no longer infect cells in the body. There was a need to find new vaccines to prevent CMV infections in people with immune systems with reduced strength.

ASP0113 was a new vaccine being studied. Researchers wanted to see if it would prevent CMV infections in people who had received a kidney transplant. In this study, people received either ASP0113 or a placebo after they received their new kidney. A placebo is a dummy injection that looks like ASP0113, but does not have any vaccine in it.

The study started in November 2013 and ended in November 2020. It was a 2-part study: the first period was a primary period for about 1 year. The second period was a follow-up period for 4 ½ years. The sponsor of this study (Astellas) reviewed all the study information and created reports of the results in both periods. This is a summary of both the primary study period and the follow up period.

What were the main questions the study helped answer?

- How many people had a CMV infection in the primary study period (first year) after they received either the ASP0113 vaccine or a placebo?
- Did people have any medical problems the first year from receiving ASP0113?
- Did people have any long term effects from receiving ASP0113?

What kind of study was this and who took part in it?

This was a double-blinded study. That means that the people in the study and the study doctors did not know who took which of the study medicines. This helps make study results fair and unbiased.

This study included adults, aged 18 years or more. They had received a kidney transplant about a month prior to entering the study. These people did not have cytomegalovirus (CMV) at the time of their kidney transplant. Their new kidney came from either a living donor or one who had passed away. The kidney they received came from a donor who tested positive for CMV after donating the kidney.

The table below shows some information about the people in the study. 149 people received at least 1 injection of a study vaccine in this study.

	Number of People
Age Group	
Aged less than 65 years	128
Aged 65 years or older	21
Sex	
Men	109
Women	40

Where did the study take place?

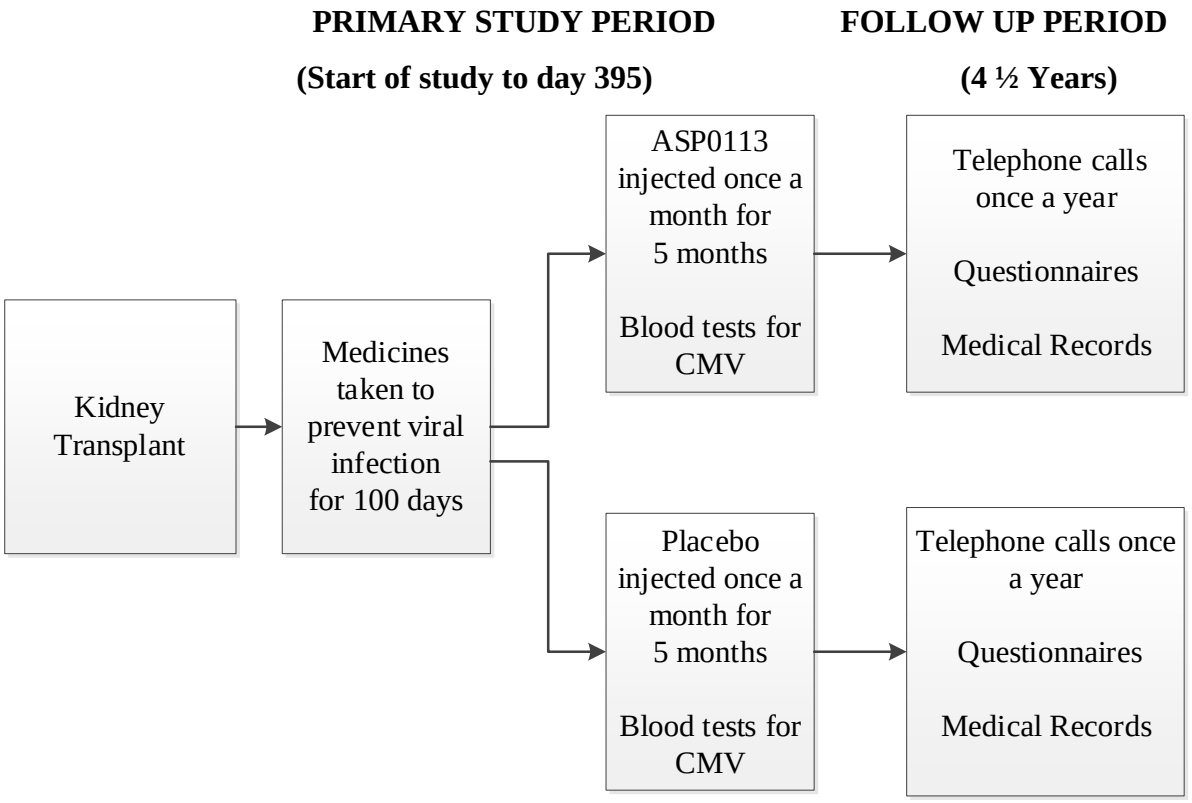
This study took place at 52 clinics in several countries.

	Number of People
Clinic Location	
European Union Countries (*at the time of the study*)	39
France	15
Germany	16
Spain	8
Outside European Union	110
Australia	11
Canada	7
United States	92

What happened during the study?

After their kidney transplant and within 10 days, people received a medicine to prevent viral infections. The study doctor checked the people to see if they could be in the study. If they could, about 30 days after their kidney transplant, they received either ASP0113 or a placebo

by chance alone. A placebo is a dummy injection that looks like ASP0113, but does not have any vaccine in it. The following diagram shows what happened during the study.



Frequent blood tests looked for cytomegalovirus (CMV) infections. This helped the study doctors determine if ASP0113 prevented CMV infections the first year after receiving it. People did not receive any ASP0113 or placebo during the follow up period. They received a telephone call once a year. They completed questionnaires. Their medical records were available to the researchers. This helped the study doctors determine if there were any long term effects caused by ASP0113.

What were the study results?

Primary Study Period

146 people had at least 1 test measuring how much CMV was in their blood. 73 of these people received ASP0113 and 73 people received placebo.

How many people had a CMV infection?

ASP0113	Placebo
26 people (35.6%, 26 out of 73 people)	30 people (41.1%, 30 out of 73 people)

Statistical testing showed that this difference between the groups was likely to be due to chance. ASP0113 did not help prevent cytomegalovirus (CMV) infections during the first year after a kidney transplant.

What adverse reactions did people have in this study during the primary period?

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 people have while they are in the study. These 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.

In this study, 59 people (78.7% or 59 out of 75 people) who received at least 1 injection of ASP0113 had adverse reactions in the primary study period.

In this study, 40 people (54.1% or 40 out of 74 people) who received at least 1 injection of placebo had adverse reactions in the primary study period.

The table below shows the most common adverse reactions experienced by people during the primary study period.

Adverse Reaction in Primary Study Period	ASP0113 (out of 75 people)	Placebo (out of 74 people)
Pain at the injection site	44 (58.7%)	17 (23.0%)
Fatigue or tiredness	19 (25.3%)	12 (16.2%)
Muscle pain	17 (22.7%)	10 (13.5%)
A common virus (cytomegalovirus) present in the blood	13 (17.3%)	3 (4.1%)
Redness of the skin at the injection site	8 (10.7%)	2 (2.7%)

Note: These adverse reactions are from the primary study period. Start of the study to about 1 year and a month later.

Did any of the people in this study have serious adverse reactions?

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

In this study, 10 people (13.3%, or 10 out of 75 people) who received at least 1 injection of ASP0113 had serious adverse reactions in the primary study period.

In this study, 5 people (6.8%, or 5 out of 74 people) who received at least 1 injection of placebo had serious adverse reactions in the primary study period.

1 person who had received placebo passed away during the primary study period.

Follow Up Period

The follow up period lasted 4 ½ years. People were contacted by telephone once a year and answered questionnaires. Their medical records were available to the researchers. Routine tests to measure cytomegalovirus (CMV) were not done during this period of time. Hospital care and deaths were recorded. Results of laboratory blood tests were recorded.

Did people have any long term effects from receiving ASP0113?

During the follow up period, no one reported either hardening or redness of the skin at the injection site used earlier in the primary period.

Between the ASP0113 and placebo groups, there were no apparent trends in new cancers or cancers that returned. There were no trends in graft loss. Graft loss means the failure or loss of the new kidney. And there were no trends in infections that required hospital care. Slightly more deaths were reported in the ASP0113 group than in the placebo group: 7 in the ASP0113 group and 3 in the placebo group.

The median serum creatinine blood test was similar between the 2 groups of people. Median is a middle value in a sorted list of numbers.

People did not have long term effects from having received ASP0113.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study. You can find this summary and more information about this study 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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