Plain Language Summary of Study Results

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

Thank you!

Study Sponsor: **Astellas**

Medicine Studied: **ASP0892**

Study Number: **0892-CL-1001**

What was the study called?

A study of an ASP0892 vaccine for adults with peanut allergies.

Why was the study needed?

People who have a peanut allergy may have a severe allergic reaction to peanuts, which in some cases may be fatal. At the time of this study, there were no treatments available to stop or reduce severe allergic reactions specific to peanuts.

ASP0892 is being studied as a potential new treatment to reduce the severity of allergic reactions in people with peanut allergies. It is a vaccine that contains specific genetic code to instruct cells in the body to make harmless amounts of the peanut proteins that cause allergic reactions. This should trigger an immune response, which produces antibodies and so protect people when exposed to peanuts in the future.

This study provided more information on ASP0892 given to adults with peanut allergies.

In this study, people with mild or moderate peanut allergies were given either ASP0892 or placebo. In this study, the placebo looked like the ASP0892 vaccine without any medicine in it. The vaccines were given as injections in 1 of 2 ways; either in the skin (intradermal) or into a muscle (intramuscular).

The study started in December 2016 and ended in December 2018. Astellas reviewed all the study information and created a report of the results. This is a summary of that report.

What were the main questions this study helped answer?

- What medical problems did people in the study have within 7 days of receiving the ASP0892 or placebo vaccines?
- Did people in the study have any other medical problems from the ASP0892 or placebo vaccines?

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

This study was designed to understand the dose and how the vaccine was given that resulted in the fewest medical problems in adults.

It was done in a “randomized” and “double-blinded” way. This means:

- The vaccine each person received and the dose they were given was chosen by chance alone.
- Only the pharmacist who prepared the vaccine knew which vaccine each person was given. People taking part, the study staff and the study doctors who checked the data were not told.

Randomized and blinded studies help make the results fair and unbiased.

Information on people who took part in the study
People from 18 to 35 years old with a mild or moderate peanut allergy took part
31 people took part
17 men **14 women**
ASP0892 **or** **placebo**
25 people received ASP0892 **6 people received placebo**

Where did the study take place?

This study took place at 8 clinics in the United States.

What happened during the study?

The study doctors did a check-up to make sure each person could be in the study before they received their assigned vaccine.

Assigned vaccine
1 mg **ASP0892** ID or **placebo** ID
4 mg **ASP0892** ID or **placebo** ID
4 mg **ASP0892** IM or **placebo** IM

mg = milligrams
ID = intradermal injection – injection in the skin
IM = intramuscular injection – injection into a muscle

People in each group received up to 4 vaccines (1 vaccine every 2 weeks). They had the same dose and type of injection as in their first vaccination. They were given a diary to record information such as any medical problems they had for the first 7 days after each vaccination.

People returned to the study clinic for regular check-ups for up to 7 months after their first vaccination. During these check-ups, people were asked if they had any medical problems. Blood and urine samples were also taken.

What were the study results?

A lot of research is needed to understand how vaccines work and if they cause any medical problems. When new or existing vaccines 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 vaccine given.

When the study doctors believe a medical problem might possibly be caused by a vaccine used in a study, this is called an adverse reaction.

What medical problems did people in the study have within 7 days of receiving the ASP0892 or placebo vaccines?

The most common **adverse events** are shown below.

	ASP0892 1 mg ID	ASP0892 4 mg ID	ASP0892 4 mg IM	Placebo ID	Placebo IM
Pain at injection site	3 out of 8 (37.5%)	6 out of 8 (75.0%)	7 out of 8 (87.5%)	1 out of 4 (25.0%)	1 out of 2 (50.0%)
Fatigue or tiredness	4 out of 8 (50.0%)	3 out of 8 (37.5%)	4 out of 8 (50.0%)	3 out of 4 (75.0%)	1 out of 2 (50.0%)
Headache or head pain	2 out of 8 (25.0%)	1 out of 8 (12.5%)	3 out of 8 (37.5%)	1 out of 4 (25.0%)	1 out of 2 (50.0%)
Nausea or urge to vomit	2 out of 8 (25.0%)	1 out of 8 (12.5%)	3 out of 8 (37.5%)	1 out of 4 (12.5%)	0
Muscle pain	0	4 out of 8 (50.0%)	1 out of 8 (12.5%)	1 out of 4 (25.0%)	1 out of 2 (50.0%)
Redness of skin at injection site	2 out of 8 (25.0%)	3 out of 8 (37.5%)	0	0	0
Diarrhea	2 out of 8 (25.0%)	0	2 out of 8 (25.0%)	0	0
Swelling at injection site	1 out of 8 (12.5%)	2 out of 8 (25.0%)	0	0	0

mg = milligrams
ID = intradermal injection – injection in the skin
IM = intramuscular injection – injection into a muscle

Did people in the study have any other medical problems from the ASP0892 or placebo vaccines?

People who experienced **adverse reactions** during this study are shown below.

	ASP0892 (all groups)	Placebo (all groups)
Adverse reaction	9 out of 24 (37.5%)	1 out of 6 (16.7%)

The most common adverse reaction was itchiness at the injection site (for ASP0892 groups only).

No one reported severe anaphylactic reactions to either the ASP0892 or placebo vaccines during the study.

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.

No one experienced an adverse reaction that was considered serious.

Where can I learn more about this study?

This document is a short summary of the main results from this study.

The full name for the study is: A Phase 1, Randomized, Placebo-Controlled Study to Evaluate Safety, Tolerability and Immune Response in Adults Allergic to Peanut after Receiving Intradermal or Intramuscular Administration of ASP0892 (ARA-LAMP-vax), a Single Multivalent Peanut (Ara h1, h2, h3) Lysosomal Associated Membrane Protein DNA Plasmid Vaccine.

You can find this summary and more information about this study at

https://www.trialsummaries.com/

Further information can be found at the following website:

https://clinicaltrials.gov/ ClinicalTrials.gov Identifier: NCT02851277

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 Inc.
1 Astellas Way
Northbrook, IL 60062
USA

This summary was written by Astellas in March 2022.