# Plain Language Summary of Study Results

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

**Thank you!**

## What was the study called?

A phase 1 study of ASP1650 in women with ovarian cancer.

## Why was this study needed?

The ovaries are part of a woman's reproductive system. They produce a woman's eggs and female hormones. Ovarian cancer is when cancerous tumors form on the ovaries or in the surrounding areas. CLDN6 is a protein that is sometimes found in cancerous tumors. Blood tumor markers, like CA-125, may be increased. Advanced ovarian cancer means the cancer has spread from the ovaries to nearby tissue or lymph nodes. Standard treatments for ovarian cancer may include surgery or chemotherapy. These treatments may not work in all women. Or the cancerous tumors may come back after treatment is finished. When this happens, it is called recurrent ovarian cancer. New treatments for this type of ovarian cancer are needed.

Researchers in this study were interested in finding better ways to treat advanced ovarian cancer. The study medicine, ASP1650, was studied for treating women with advanced ovarian cancer.

The study started in January 2014 and ended in October 2015. 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 were the main questions the study helped answer?

- What medical problems did these women have from receiving ASP1650?
- What was the highest dose of ASP1650 that women with ovarian cancer could tolerate?

### What other questions did this study helped answer?

- Did ASP1650 help to treat the women's ovarian cancer?

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

This was a phase 1 study. The aim of a phase 1 study is to learn the best dose for a study medicine. This is usually the dose that people can receive without getting medical problems from the medicine. Phase 1 studies usually include healthy people but can include people with certain health conditions. Women with advanced ovarian cancer were in this study. Their tumor had returned after prior therapy.

This was an open label study. That means that each woman in this study and the study doctors knew that woman received ASP1650.

Women who had a confirmed diagnosis of advanced ovarian cancer could take part in the study. In addition, they had the following:

- Their tumors contained CLDN6.
- They had symptoms after 2 cycles of chemotherapy that contained platinum. Or, the tumors returned within 6 months of having chemotherapy that contained platinum. Or, their tumors had returned after 2 prior standard therapies. One of the 2 therapies contained platinum. Or, they had no symptoms but their blood test for CA-125 was increased. And, they had 1 standard therapy.
- They were active or they could perform light daily activities. Or they were able to walk and capable of all self-care, but unable to carry out any work activities. And they were up and about more than half of the time they were awake.
- They were expected to live for more than 12 weeks.

Additional information on the women is below:

| Age | Number of Women in the study |
|---|---|
| **The women were from 53 to 83 years of age**<br><br>**Median Age: 65 years (**the middle number in a sorted list) | **42** |
| One woman joined the study but did not take any ASP1650 before leaving. | |

# Where did the study take place?

This study took place in Germany and Belgium.

| Country where the study took place | Number of Women |
|---|---|
| European Union Countries (at the time of the study) | **42** |
| **Belgium** | **17** |
| **Germany** | **25** |

# What happened during the study?

**During the study**, the study doctor did a check-up of the women at several study visits. At the first visit, women were checked to see if they could be in the study. Women received ASP1650 through a vein in their arm. This is called an infusion.

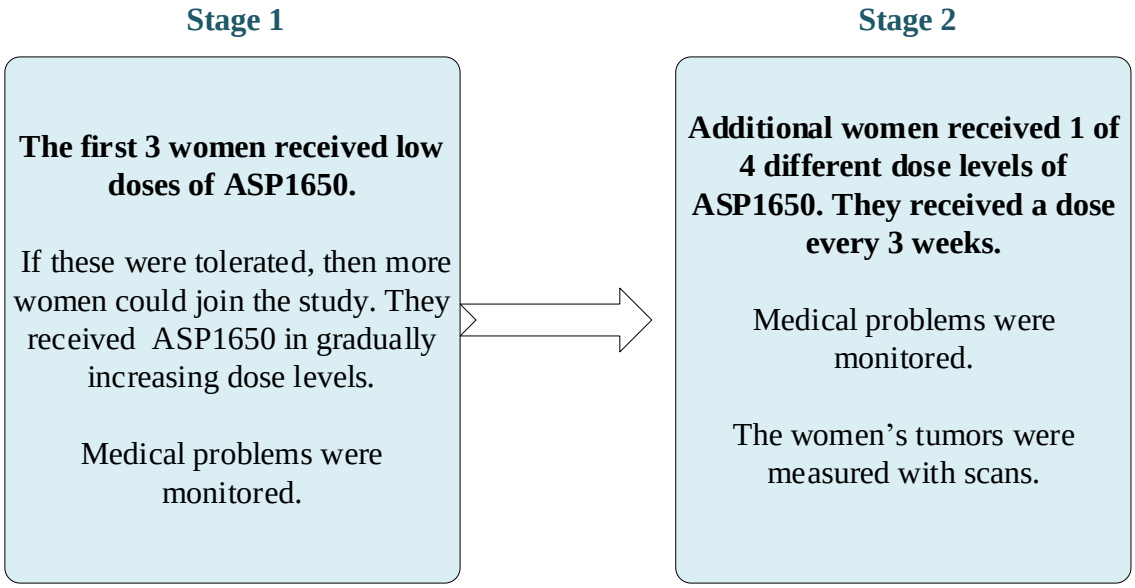
**The study had 2 stages**. In stage 1, ASP1650 was given at a low dose for the first time in people. There was at least 7 or more days between the first woman who received a dose and the second woman. In stage 2, the dose level of ASP1650 was gradually increased until the best dose was found.

**Throughout the study**, the women were checked regularly for medical problems. A dose was tolerated if women did not have certain medical problems caused by the study medicine. Or if they did not have certain abnormal laboratory tests caused by the study medicine.

The women's tumors were measured with scans. This allowed the study doctors to monitor their ovarian cancer.

**Women could take ASP1650 until:** their cancer got worse; they had medical problems they could not tolerate; they asked to stop treatment; the study doctor decided that continuing treatment was no longer in the woman's best interest.

The following diagram shows what happened in the study:




# What medical problems did these women have from receiving ASP1650?

## *What adverse reactions did women have in this study?*

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 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.

In this study, 30 women (71.4%, or 30 out of 42 women) who received at least 1 dose of ASP1650 had adverse reactions.

The table below shows the most common adverse reactions experienced by women in this study.

| Adverse Reaction | ASP1650 (out of 42 women) |
|---|---|
| **Any adverse reaction** | 30 (71.4%) |
| **Fatigue** | 7 (16.7%) |
| **Nausea** | 6 (14.3%) |

### *Did any of the women 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, 3 women (7.1%, or 3 out of 42 women) who received at least 1 dose of ASP1650 had serious adverse reactions.

In this study, death from a woman's ovarian cancer getting worse was not considered a serious adverse event. It was an indication of whether the treatment worked or didn't work. Most of the women in this study passed away because their ovarian cancer got worse. 3 women passed away due to an adverse event. None of the events were judged by the study doctor to be caused by ASP1650.

## What were the study results?

The question that this study helped answer:

### *What was the highest dose of ASP1650 that women with ovarian cancer can tolerate?*

The women in this study tolerated ASP1650. The study doctors could not say what the highest tolerable dose was. This was because only 1 medical problem was considered unacceptable enough to limit a dose. More information was needed to determine what the highest dose could be.

## What were the other study results?

The other question that this study helped answer:

### *Did ASP1650 help the women's ovarian cancer?*

This was not the main question that this study helped answer. The researchers did not compare ASP1650 to another standard treatment in treating women with ovarian cancer in this study. Study doctors found there was limited evidence that ASP1650 worked to shrink or get rid of the women's cancerous tumors.

## 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 https://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 Inc.
1 Astellas Way
Northbrook, IL 60062
USA