Plain Language Summary of Study Results

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

What was the study called?

This study assessed the safety and efficacy of ASP1650 in men with incurable germ cell tumors.

Why was the study needed?

A germ cell is a type of cell that forms as an unborn baby (fetus) grows and develops. These cells then grow to become sperm in the testicles or eggs in the ovaries. Tumors can develop from a germ cell. Tumors are abnormal growths in the body. They can be either benign or malignant. Benign tumors are not cancer. Malignant means the tumor is cancerous and may spread to other parts of the body. Cancerous tumors can be treated with surgery, x-rays or chemotherapy. These treatments may not work in all people. Or the tumors may return after treatment is finished. New treatments for germ cell tumors are needed.

ASP1650 is a new medicine being studied in men with germ cell tumors which did not respond to other available treatment.

The study started in March 2019 and ended in October 2020. 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 is the highest dose of ASP1650 that can be tolerated in men with germ cell tumors?
- Did the tumors in these men decrease in size?
- What medical problems did these men have from receiving ASP1650?

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

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

Men who had been diagnosed with cancerous germ cell tumors could take part in the study. Their tumors had returned after prior chemotherapy that contained platinum. The men were not able to have other available treatment. Or there was no available treatment for them. One of the most common types of cancer with these tumors is cancer of the testis.

The men in this study were less than 65 years of age:

- Their age ranged from 20 to 58 years.
- Their average age was about 37 years.

Where did the study take place?

This study took place at 3 clinics in the United States. 19 men were in the study and received at least 1 dose of ASP1650.

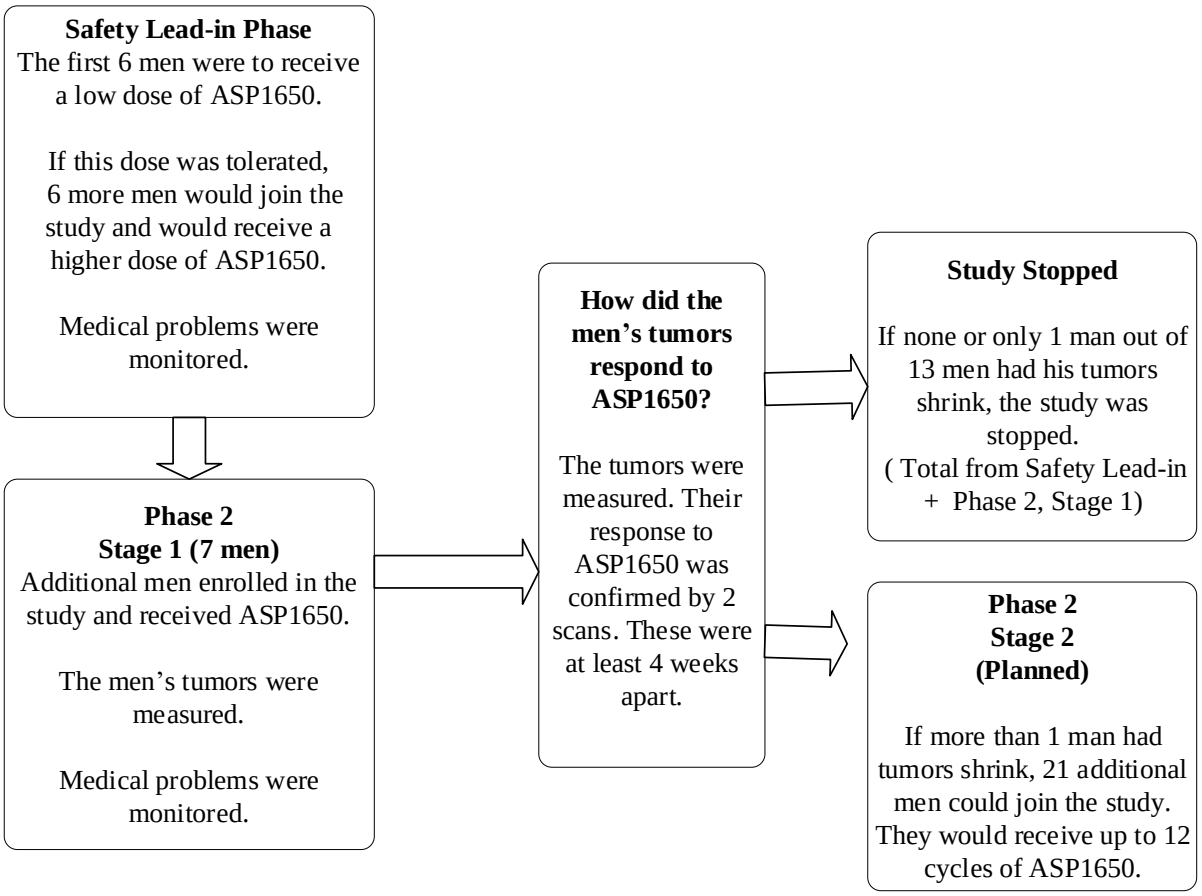
What happened during the study?

During the study, the study doctor did a check-up of the men at several study visits. At the first visit, men were checked to see if they could be in the study. The study had 2 phases: A safety lead-in phase and a phase 2. Phase 2 had a 2-stage design. Throughout the study, the men were checked regularly for medical problems.

Men who could be in the study received ASP1650 through a vein in their arm. This is called an infusion. The men received a dose once during a 14-day treatment cycle. A dose was tolerated if men did not have certain medical problems caused by ASP1650. Or if men did not have certain abnormal laboratory tests caused by ASP1650.

Men 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 man's best interest; the study was stopped.

The diagram below shows the plan for the study:



What were the study results?

ASP1650 was tolerated by the men in the study.

None of the men's tumors were reduced by ASP1650. Since ASP1650 did not help control the tumors, the study was stopped early. No one entered the planned phase 2, stage 2 part of the study.

What adverse reactions did men 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, 7 men (36.8%, or 7 out of 19 men) had adverse reactions.
- The most common adverse reaction in the study was fatigue or tiredness. This was seen in 2 men (10.5%, or 2 out of 19 men).

Did any of the men 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, 1 man (5.3%, or 1 man out of 19 men) had a serious adverse reaction. The serious adverse reaction was decreased appetite.
- 8 men passed away during the study. None of the deaths were thought to be caused by ASP1650.

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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