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 Multicenter, Open-label, Randomized Phase 2 Study of AGS-16C3F vs Axitinib in Metastatic Renal Cell Carcinoma

Why was the Study Needed?

Renal cell carcinoma is a type of kidney cancer. There are different types of renal cell carcinoma. The types of this cancer are named by how the tumor cells look under a microscope (histology). One type is clear cell renal cell carcinoma. Another type is nonclear cell. The spread of cancer cells from the place where they first formed to another part of the body is called metastatic cancer.

Several medicines are available to slow the growth of renal cell carcinoma. One of these available medicines is called axitinib. However, not all of the available medicines may work well in all people. Most of the available medicines for renal cell carcinoma are for the clear cell type. There are not many medicines available for the nonclear cell type.

People in this study received or took one of 2 medicines. One was an experimental medicine called AGS-16C3F. The other was an available one called axitinib.

The study started in May 2016. By August 2019, most people had completed the study. Or they had stopped taking part in it. 8 people continue in the study because they are either still taking one of the study medicines or the progress of their disease is still being followed. The sponsor of this study (Astellas) reviewed all the study information up to August 2019. They created a report of these results. This is a summary of that report.

What were the main questions the study helped answer?

- Which of the 2 study medicines made progression free survival longer? This is the length of time from the start of study medicine until the cancer got worse, or the person died (of any cause).
- Did people have any medical problems from the study medicines?

What Kind of Study was this and Who Took Part in It?

This was an "open-label" study. That means that each person and the study doctors knew which study medicine that person received.

People with confirmed renal cell carcinoma could be in the study. Their cancer had spread to other parts of their bodies (metastatic cancer). Their cancer was getting worse, on or after their prior treatment. Their renal cell carcinoma could be either clear or nonclear cell type.

If it was clear cell type, they had at least 2 prior treatments that failed. If it was nonclear cell type, they had at least 1 prior treatment that failed. The people in the study were active or they could perform light daily activities.

Most of the people in the study were men.

	Number of People (out of 131 people)
Age Group	
Aged less than 65 years	86
Aged 65 years or older	45
Sex	
Men	96
Women	35

What Happened during the Study?

During the study, the study doctor did a check-up of the people at several study visits. At the first visit, they were checked to see if they could be in the study. People who could be in the study were picked for 1 of 2 treatment groups by chance alone.

People received or took either AGS-16C3F or axitinib.

- People picked for AGS-16C3F group received 1.8 milligrams of it for every kilogram of their body weight once every 3 weeks. They received it slowly through a tube inserted into a vein. This is called an infusion.
- People picked for axitinib group took 5 mg of it by mouth twice a day.

People could take study medicine until their cancer got worse, they had unwanted effects they could not tolerate or they asked to stop treatment. Or the study doctor decided that continuing treatment was no longer in the person's best interest.

Where did the Study Take Place?

This study took place at 26 clinics in the United States and Canada. 133 people were in the study. Out of these, 131 people either received or took at least 1 dose of a study medicine. 66 people received AGS-16C3F and 65 people took axitinib. 8 people (6.0%, or 8 out of 131) continue in the study as of August 2019.

What Were the Study Results?

The study measured the length of time from when the person started the study until the time the cancer got worse, or the person died (of any cause). This length of time is called progression free survival.

Which of the 2 study medicines made progression free survival longer?

People who received AGS-16C3F had a shorter progression free survival time. This means their cancer became worse or they died (of any cause) sooner than people who took axitinib.

A median is the middle value in a list of numbers. The median number of months before a person was worse or died (of any cause) was 2.9 months in the AGS-16C3F group. The median number of months in the axitinib group was 5.7 months.

8 people chose to continue in the study after August 2019. 5 people in the axitinib group and 3 people in the AGS-16C3F group. They could continue the study if they were still taking or receiving one of the study medicines. Or, they agreed to continue to be followed to see if their cancer became worse or they died.

What Adverse Reactions did People 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 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.

112 people (85.5%, or 112 out of 131 people) had adverse reactions in this study.

The table below shows the most common adverse reactions experienced by people who took at least 1 dose of study medicine in this study

Adverse Reaction	AGS-16C3F (out of 66 people)	Axitinib (out of 65 people)
Nausea or the urge to vomit	23 (34.8%)	16 (24.6%)
Fatigue or tiredness	22 (33.3%)	26 (40.0%)
Blurred vision	18 (27.3%)	2 (3.1%)
Diarrhea	6 (9.1%)	26 (40.0%)
High blood pressure	2 (3.0%)	26 (40.0%)
Hoarse or rough voice	0	21 (32.3%)
Decreased appetite	9 (13.6%)	17 (26.2%)

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.

13 people (9.9%, or 13 out of 131) in this study had serious adverse reactions: 7 people who received AGS-16C3F and 6 people who took axitinib.

4 people in the study passed away. None of the deaths were because of the study medicines.

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 online at http://www.astellasclinicalstudyresults.com.

No other studies of AGS-16C3F in renal cell carcinoma are planned at this time.

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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