Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer, Inc.

Medicine(s) Studied: Sasanlimab (PF-06801591)

Protocol Number: B8011001

Dates of Study: 10 February 2016 to 19 November 2020

Title of this Study: A Dose Escalation Study Of PF-06801591 In Melanoma, Head And Neck Cancer (SCCHN), Ovarian, Sarcoma, Non-Small Cell Lung Cancer, Urothelial Carcinoma or Other Solid Tumors

[A Phase 1, Open-Label, Dose Escalation and Expansion Study of PF-06801591 in Patients With Locally Advanced or Metastatic Melanoma, Squamous Cell Head and Neck Cancer, Ovarian Cancer, Sarcoma, Non-small Cell Lung Cancer, Urothelial Carcinoma or Other Solid Tumors]

Date(s) of this Report: 15 June 2021

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation. This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is Sasanlimab?

Sasanlimab (sah-SAN-lih-mab) is a new experimental drug for cancer treatment that is currently not approved for sale or for use outside of a clinical trial. Sasanlimab is a type of medicine called an "antibody". Antibodies are special proteins made by the immune system that recognize and stick to specific proteins on the surface of germs or cells. Sasanlimab recognizes a protein called "PD-1" that is located on your immune cells. Sasanlimab blocks PD-1 from interacting with another protein, "PD-L1", located on the surface of tumors. Blocking this interaction may help the immune system slow or stop the growth of cancer cells.

What was the purpose of this study?

This study was divided into 2 parts. The main purpose of Part 1 of this study was to learn about the safety of sasanlimab, and to find the best dose of sasanlimab to use to treat cancer in Phase 2 trials. To do this, the researchers asked,

- **What medical problems did participants have while taking sasanlimab?**
- **What dose-limiting toxicities (DLTs) did participants have when taking sasanlimab?**

DLTs are certain medical problems caused by taking sasanlimab, which require the patient to lower the dose or stop taking the medicine temporarily or permanently. These medical problems could also stop the use of the drug at that dosage in all patients.

The main purpose of Part 2 of this study was to learn more about the safety of sasanlimab, and to measure if any of the patients' cancer got better during the study. To do this, the researchers asked,

- **What medical problems did participants have while taking sasanlimab?**
- **How many participants had their cancer get better when taking sasanlimab?**

Researchers wanted to know:

- **What medical problems did patients have while taking sasanlimab?**
- **What dose-limiting toxicities (DLTs) did patients have when taking sasanlimab in Part 1 of the study?**
- **How many patients had their cancer get better when taking sasanlimab in Part 2 of the study?**

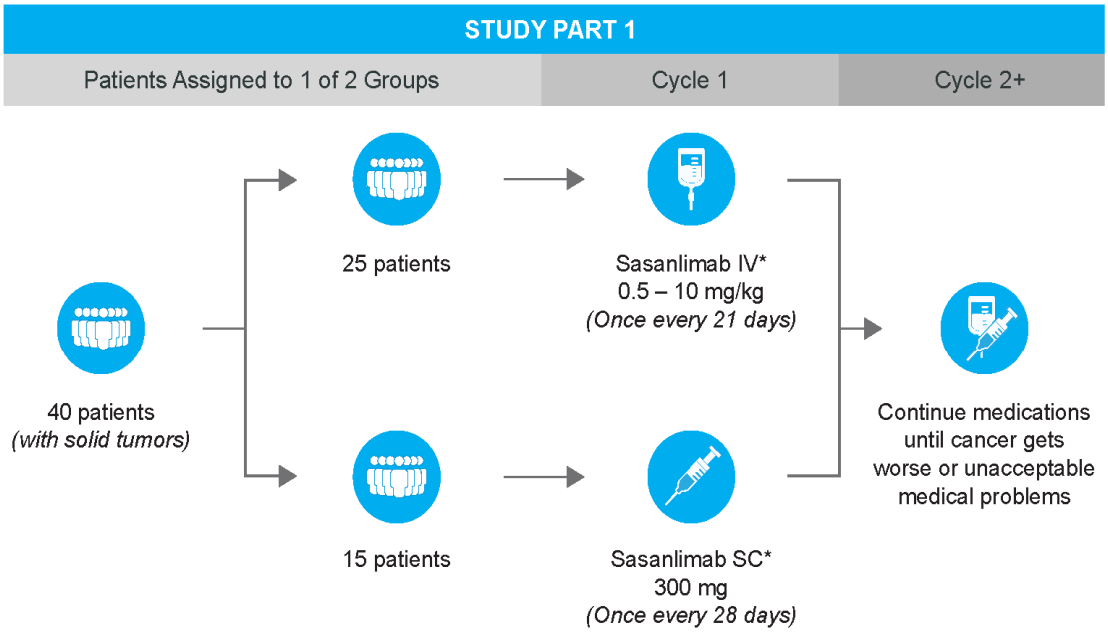
What happened during the study?

How was the study done?

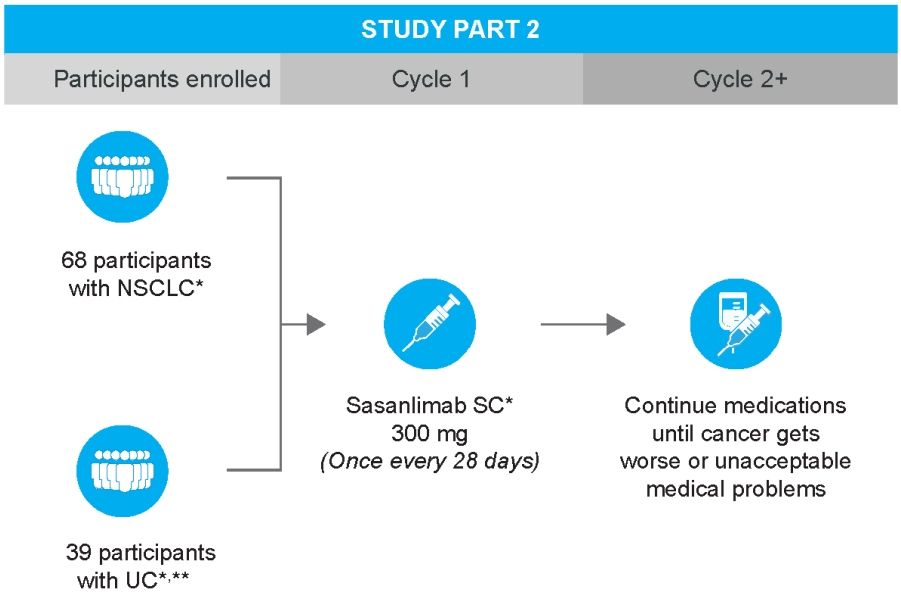
During Part 1, researchers tested different doses of sasanlimab on a group of participants with solid tumors to learn about the safety of sasanlimab and find the best dose of sasanlimab to treat cancer in future trials. Participants were given sasanlimab either by infusion into a vein (intravenously, or "IV") at a dose of 0.5 to 10 mg/kg of body weight every 21 days, or 300 mg of sasanlimab by injection under the skin (subcutaneously, or "SC") every 28 days.

During Part 2, researchers tested a group of participants with either non-small cell lung cancer ("NSCLC") or cancer of the lining of the urinary tract (urothelial cancer, or "UC") to learn more about the safety of sasanlimab. They also measured the size of the participants' tumors to see if their cancer got better or worse during treatment. Participants were given 300 mg of sasanlimab SC every 28 days.

This study was "open-label", meaning that the doctors and participants knew what treatment they were being given. The study design is shown in the graphics on the next page.



*IV = given by injection into a vein; SC = given by injection underneath the skin



*NSCLC = non-small cell lung cancer; SC = given by injection underneath the skin;
UC = urothelial cancer. ** One (1) participant with UC enrolled but was not treated.

Where did this study take place?

The Sponsor ran this study at 55 locations in 8 countries in Europe, Asia, and North America.

When did this study take place?

It began on 10 February 2016 and ended on 19 November 2020.

Who participated in this study?

Part 1 of the study included adult participants who were diagnosed with certain types of solid tumors of the skin, head and neck, ovaries, connective tissues, lungs, or lining of the urinary tract that was locally advanced (the cancer had grown outside of the organ it had started in but had not yet spread to distant parts of the body) or metastatic (spread to distant parts of the body).

Part 2 of the study included adult participants who were diagnosed with either non-small cell lung cancer (NSCLC) or urothelial carcinoma (UC) that was locally advanced or metastatic (spread to other parts of the body).

- A total of 12 men participated in Part 1 and 78 men participated in Part 2
- A total of 28 women each participated in Part 1 and Part 2
- All participants were between the ages of 26 and 88

Of the 40 participants who started Part 1 of the study and received sasanlimab, 1 finished treatment and 6 finished the study. Of the 106 participants who started Part 2 of the study and received sasanlimab, 10 finished treatment and 15 finished the study. The most common reason for participants stopping treatment during Part 1 or Part 2 was because their cancer got worse, and the most common reason for leaving the study was because the participant passed away.

How long did the study last?

Study participants received an average of 12 cycles of treatment in Part 1 of the study, and 9 cycles of treatment in Part 2 of the study. The entire study took 4 years and 9 months to complete.

When the study ended in November 2020, the Sponsor reviewed the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Were any dose-limiting toxicities (DLTs) reported during Part 1 of the study?

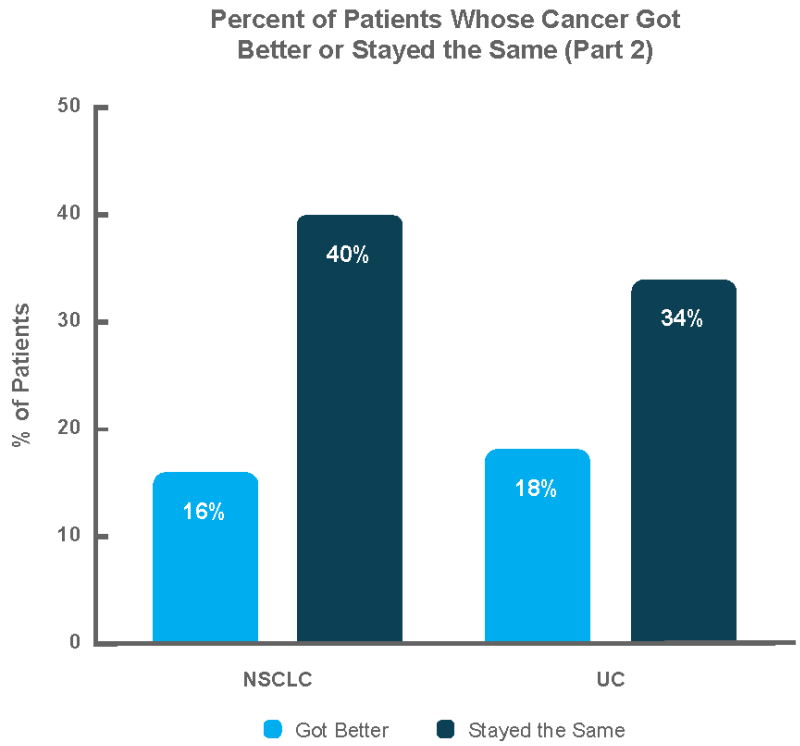
No DLTs were reported in the 40 participants treated with sasanlimab during Part 1 of the study.

How many participants had their cancer get better when taking sasanlimab during Part 2 of the study?

To answer this, the researchers measured the "Objective Response Rate", which is the percentage of participants whose cancer got better (their tumor shrank or disappeared) during Part 2 of the study. They also recorded the percentage of participants whose cancer stayed the same or got worse. The results are shown in the graph on the next page.

How many participants had their cancer get better when taking sasanlimab during Part 2 of the study?

- A total of 16% of participants with NSCLC and 18% of participants with UC had their cancer get better during Part 2 of this study. In addition, 40% of participants with NSCLC and 34% of participants with UC had their cancer stay the same during Part 2 of this study.



This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

A total of 39 out of 40 (98%) participants in Part 1 and 98 out of 106 (93%) participants in Part 2 of this study had at least 1 medical problem. A total of 1 participant in Part 1 and 11 participants in Part 2 stopped taking the study treatment because of medical problems. The most common medical problems – those reported by more than 10% of participants in Part 1 or Part 2 – are described in the table on the next page.

Instructions for Understanding Table 1 and Table 2.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 10% of participants are listed. Table 2 lists serious medical problems reported by more than 1 participant during the study.
- The **2nd** and **3rd** columns tell how many of the participants taking the study medication in Part 1 or Part 2 reported each medical problem. Next to this number is the percentage of the participants taking the study medication who reported the medical problem.
- Using these instructions, you can see in Table 1 that 9 out of the 40 participants (23%) taking sasanlimab in Part 1 of the study reported a low blood cell count.

Table 1. Commonly reported medical problems by more than 10% of study participants in Part 1 or Part 2 of the study

Medical Problem	Part 1 Sasanlimab 0.5 – 10 mg/kg IV or 300 mg SC (40 Participants)	Part 2 Sasanlimab 300 mg SC (106 Participants)
Low red blood cell count	9 out of 40 participants (23%)	25 out of 106 participants (24%)
Overactive thyroid	2 out of 40 participants (5%)	11 out of 106 participants (10%)
Abdominal pain	5 out of 40 participants (13%)	3 out of 106 participants (3%)
Constipation	13 out of 40 participants (33%)	6 out of 106 participants (6%)
Diarrhea	12 out of 40 participants (30%)	9 out of 106 participants (9%)
Nausea	12 out of 40 participants (30%)	8 out of 106 participants (8%)
Vomiting	12 out of 40 participants (30%)	1 out of 106 participants (1%)
Feeling dizzy	2 out of 40 participants (5%)	13 out of 106 participants (12%)
Feeling tired	18 out of 40 participants (45%)	11 out of 106 participants (10%)
Swelling of mucus producing tissues	5 out of 40 participants (13%)	0 out of 106 participants
Fever	2 out of 40 participants (5%)	11 out of 106 participants (10%)
Nose, sinus, or throat infection	6 out of 40 participants (15%)	4 out of 106 participants (4%)
Urinary tract infection	6 out of 40 participants (15%)	8 out of 106 participants (8%)
Liver enzyme levels increased (AST)	5 out of 40 participants (13%)	9 out of 106 participants (9%)

Blood creatinine levels increased	6 out of 40 participants (15%)	6 out of 106 participants (6%)
Weight loss	5 out of 40 participants (13%)	6 out of 106 participants (6%)
Decreased appetite	13 out of 40 participants (33%)	12 out of 106 participants (11%)
Dehydration	7 out of 40 participants (18%)	4 out of 106 participants (4%)
Low blood potassium	6 out of 40 participants (15%)	2 out of 106 participants (2%)
Joint pain	8 out of 40 participants (20%)	8 out of 106 participants (8%)
Back pain	8 out of 40 participants (20%)	9 out of 106 participants (9%)
Dizziness	5 out of 40 participants (13%)	4 out of 106 participants (4%)
Anxiety	6 out of 40 participants (15%)	0 out of 106 participants
Cough	10 out of 40 participants (25%)	8 out of 106 participants (8%)
Difficulty breathing	11 out of 40 participants (28%)	10 out of 106 participants (9%)
Itchy skin	4 out of 40 participants (10%)	12 out of 106 participants (11%)

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

A total of 13 out of 40 participants (33%) had serious medical problems in Part 1. A total of 31 out of 106 participants (29%) had serious medical problems in Part 2. Most were not thought to be related to the study treatment. A total of 28 out of 40 participants (70%) in Part 1 and 54 out of 106 participants (51%) in Part 2 passed away during the study, mostly due to the participants' cancer getting worse.

The serious medical problems reported by more than 1 participant during the study are shown in Table 2 on the next page.

Table 2. Serious medical problems by more than 1 participant during the study

Serious Medical Problem	Part 1 Sasanlimab 0.5 – 10 mg/kg IV or 300 mg SC (40 Participants)	Part 2 Sasanlimab 300 mg SC (106 Participants)
Low red blood cell count	0 out of 40 participants	2 out of 106 participants (2%)
Difficulty swallowing	1 out of 40 participants (3%)	1 out of 106 participants (1%)
Blockage in small intestines	2 out of 40 participants (5%)	0 out of 106 participants
Bleeding in esophagus, stomach, or small intestines	2 out of 40 participants (5%)	0 out of 106 participants
Cancer got worse	4 out of 40 participants (10%)	5 out of 106 participants (5%)
Pneumonia	1 out of 40 participants (3%)	1 out of 106 participants (1%)
Blood infection	1 out of 40 participants (3%)	1 out of 106 participants (1%)
Increased liver enzymes in blood	0 out of 40 participants	2 out of 106 participants (2%)

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT02573259**
www.clinicaltrialsregister.eu	Use the study identifier **2016-003314-27**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B8011001**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for study participants.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help study participants, and you
helped us to do that!