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 patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	Pfizer Inc.
Medicine(s) Studied:	PF-06936308
Protocol Number:	C3621001
Dates of Study:	27 November 2018 to 27 September 2021
Title of this Study:	Vaccine-Based Immunotherapy Regimen-2 (VBIR-2) Treatment in Patients with Advanced Lung and Breast Cancer [A Phase 1 Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Doses and Treatment Intensification of a Vaccine-Based Immunotherapy Regimen-2 (VBIR-2) (PF-06936308) for Advanced Non-Small Cell Lung Cancer and Metastatic Triple-Negative Breast Cancer]
Date(s) of this Report:	23 May 2022

– 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 advanced lung and breast cancer?

The participants in this study had cancer that was either non-small cell lung cancer (NSCLC) or triple negative breast cancer (TNBC). These are special kinds of cancer that affect the lung or the breast. Both cancer types were advanced and/or metastatic. This means the cancer had spread to other areas of the body from the lung or the breast. This makes the cancer very difficult to treat and the person will usually pass away from the cancer.

What is Vaccine-Based Immunotherapy Regimen 2?

Vaccine-Based Immunotherapy Regimen-2 (VBIR-2) is a new type of treatment being tested in patients with cancer that consists of 4 different components. Treatments are given by injection (either under the skin or into the muscle). One of the main defenses of cancer cells is the ability to hide from and avoid being destroyed by the body's immune system. The aim of VBIR-2 is to boost the participant's immune system to help it destroy some of the cancer cells.

VBIR-2 includes a cancer vaccine and a cancer vaccine booster (or booster). The cancer vaccine works to try and train immune cells in the body to recognize proteins that are used by cancer cells. Immune cells are cells that fight infections and cancer. Both the cancer vaccine and the booster work in a similar way. Once immune cells have been trained to recognize proteins used by the cancer cell, it may be able to kill that cancer cell.

VBIR-2 also includes tremelimumab and sasanlimab. These treatments are special types of protein known as "immune checkpoint inhibitors". These treatments may stop cancer cells from preventing or turning down the body's own immune response. This could mean the body's immune system is better able to see and therefore kill the cancer cell.

What was the purpose of this study?

This study looked at the safety and tolerability of VBIR-2 treatment in participants with advanced cancer. The researchers did this by giving participants increasing doses of VBIR-2 and seeing if there were any dose limiting toxicities (DLTs) after treatment with VBIR-2 as well as looking at the general safety of this treatment. DLTs are medical problems that can be seen at some doses of cancer treatments; if DLTs are seen, this means that the dose of the drug needs to be reduced or stopped as it is making the patient very ill. If a patient experiences a DLT, the cancer treatment is often delayed until the patient's body can recover.

Researchers wanted to know:

- **Did participants given VBIR-2 treatment have DLTs?**
- **What medical problems did participants have during the study?**

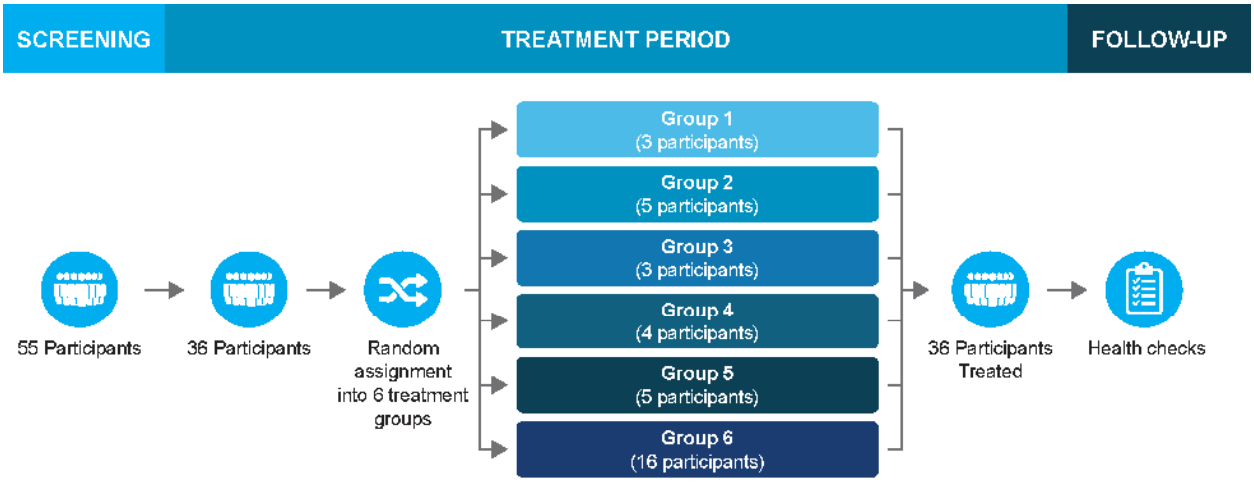
What happened during the study?

How was the study done?

Researchers tested VBIR-2 on a group of participants with advanced NSCLC or metastatic TNBC to learn about the tolerability and safety of this treatment. This was done by looking first at the safety of the vaccine and booster components of VBIR-2 and then at what would happen when the third (tremelimumab) and fourth (sasanlimab) component of the VBIR-2 treatment were added. This was Part 1 of the study.

The researchers also planned to look at the effect of VBIR-2 treatment followed by maintenance therapy in participants with NSCLC in Part 2 of the study. The study was stopped before this could happen.

Participants were split into groups and given injections of the components of VBIR-2 as shown in the following figure. The participants and researchers knew who took each type of study medication. This is known as an "open-label" study.



Group 1 - Low dose vaccine + booster
Group 2 - High dose vaccine + booster
Group 3 - High dose vaccine + booster + low dose tremelimumab
Group 4 - High dose vaccine + booster+ low dose tremelimumab + low dose sasanlimab
Group 5 - High dose vaccine + booster+ low dose tremelimumab + high dose sasanlimab
Group 6 - High dose vaccine + booster+ high dose tremelimumab + high dose sasanlimab

The cancer vaccine was given on Day 1 and then this was repeated 4 months later. The booster was given on Day 29 and then this treatment was repeated every 4 weeks for up to 8 months. Tremelimumab (if given) and sasanlimab (if given) were administered on Day 1 and then every 4 weeks. Treatment was to be continued for up to 8 months.

Researchers took samples of blood from each participant during the study and checked the participant's health.

Where did this study take place?

The Sponsor ran this study at 11 study locations in the United States (US).

When did this study take place?

It began 27 November 2018 and ended 27 September 2021.

Who participated in this study?

The study included adult participants who had advanced NSCLC or metastatic TNBC that could not be treated using standard cancer treatments, and had progressed. This means the cancer had grown resistant and stopped responding to the treatment.

- A total of 12 men participated
- A total of 24 women participated
- All participants were between the ages of 39 and 82 years

Of the 36 participants who started the study and were treated with VBIR-2, all 36 stopped treatment with VBIR-2. Most participants stopped treatment because their cancer progressed, which means the cancer started to grow again. Reasons for stopping VBIR-2 treatment were:

- Cancer progressed (67%, or 24 out of 36 participants)
- Overall health deteriorated or worsened (8%, or 3 out of 36 participants)
- Passed away (8%, or 3 out of 36 participants),
- A medical problem meant that the participant or their doctor thought it was best for the participant to stop treatment with VBIR-2 (6%, or 2 out of 36 participants)
- Other reasons (6%, or 2 out of 36 participants)
- Participant wanted to stop treatment (3%, or 1 out of 36 participants)
- Sponsor stopped the study (3%, or 1 out of 36 participants)

How long did the study last?

Study participants were in the study for up to 14 months. This included up to 8 months of treatment and 6 months of safety monitoring and health checks. The

entire study took 2 years and 10 months to complete. The Sponsor stopped this study early due to a change in development strategy.

When the study ended in September 2021, the Sponsor began reviewing 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?

Did participants given VBIR-2 treatment have dose limiting toxicities?

None of the 36 participants given VBIR-2 treatment in this study had DLTs.

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.

All 36 (100%) participants in this study had at least 1 medical problem. A total of 8 participants (22%, or 8 out of 36 participants) left the study because of medical problems. The most common medical problems – those reported by more than 10% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- 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.
- The **2nd** column tells how many of the 36 participants taking the study medication reported each medical problem. Next to this number is the percentage of the 36 participants taking the study medication who reported the medical problem.
- Using these instructions, you can see that 14 out of the 36 participants taking the study medication reported pain at the injection site.

Table 1. Commonly reported medical problems by study participants

Medical Problem	VBIR-2 Treatment (36 Participants)
Pain at the injection site	14 out of 36 participants (39%)
Shortness of breath or difficulty breathing	12 out of 36 participants (33%)
Nausea (feeling like about to vomit)	11 out of 36 participants (31%)
Feeling tired	9 out of 36 participants (25%)
Flu or cold-like illness	9 out of 36 participants (25%)
Constipation	8 out of 36 participants (22%)
Chills	7 out of 36 participants (19%)

Table 1. Commonly reported medical problems by study participants	
Medical Problem	**VBIR-2 Treatment (36 Participants)**
Fever	7 out of 36 participants (19%)
Fluid on the lungs	7 out of 36 participants (19%)
Loose stools (diarrhea)	6 out of 36 participants (17%)
Low red blood cell count	5 out of 36 participants (14%)
Being sick (vomiting)	5 out of 36 participants (14%)
Chest pain not related to the heart	5 out of 36 participants (14%)
Liver test levels increased (AST increased)	5 out of 36 participants (14%)
Decreased appetite or not feeling hungry	5 out of 36 participants (14%)
Tumor progression	5 out of 36 participants (14%)
Headache	5 out of 36 participants (14%)
Anxiety	5 out of 36 participants (14%)
Depression	5 out of 36 participants (14%)
Stomach pain	4 out of 36 participants (11%)
Cancer progression	4 out of 36 participants (11%)
Joint pain	4 out of 36 participants (11%)

Table 1. Commonly reported medical problems by study participants	
Medical Problem	**VBIR-2 Treatment (36 Participants)**
Muscle spasm	4 out of 36 participants (11%)
Muscle pain	4 out of 36 participants (11%)
Lungs not working properly	4 out of 36 participants (11%)

AST: aspartate aminotransferase.

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 18 participants (50%, or 18 out of 36 participants) had serious medical problems. The most common serious medical problems were tumor (cancer) progression or breathing problems such as lungs unable to work properly or shortness of breath. Researchers did not believe any of the serious medical problems reported by participants were related to VBIR-2 treatment.

There were also 16 participants (44%, or 16 out of 36 participants) who died because of medical problems. The participant deaths were not thought related to VBIR-2 treatment.

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.

For more details on your study protocol, please visit:

www.clinicaltrials.gov
Use the study identifier NCT03674827

www.pfizer.com/research/research_clinical_trials/trial_results
Use the protocol number C3621001

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

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