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:	Talazoparib (also known as MDV3800, BMN 673, PF-06944076)
Protocol Number:	MDV3800-13 (C3441010)
Dates of Study:	08 November 2016 to 20 July 2021
Title of this Study:	Open-Label Extension and Safety Study of Talazoparib A Single-Arm, Open-Label, Multicenter, Extended Treatment, Safety Study in Patients Treated With Talazoparib
Date(s) of this Report:	16 March 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 cancer?

Cancer is the name for a group of diseases in which abnormal cells divide without control. Most types of cancer cause solid tumors to form, which are masses of these abnormal cells.

What is talazoparib?

Talazoparib (Talzenna®) is known as a PARP inhibitor. PARP inhibitors are drugs that inhibit (stop) the normal activity of certain proteins called "Poly (ADP-ribose) polymerases", also called "PARPs". PARPs can be found in all normal and cancer cells, and are involved in the repair of DNA. Mistakes in the DNA can happen when cells divide. If the mistakes are not repaired, the cell will usually die and be replaced.

Clinical trials have shown that the use of talazoparib, as well as other PARP inhibitors, may reduce tumor size and slow tumor growth in patients with certain types of cancer. Talazoparib is given in a capsule and is taken by mouth once daily at around the same time every day.

What was the purpose of this study?

Talazoparib is now approved in the United States, the European Union, and other countries for the treatment of people with a type of cancer known as metastatic breast cancer with BRCA mutations. This study was done to learn more about the safety of talazoparib when used long term.

Researchers wanted to know:

What medical problems did participants have?

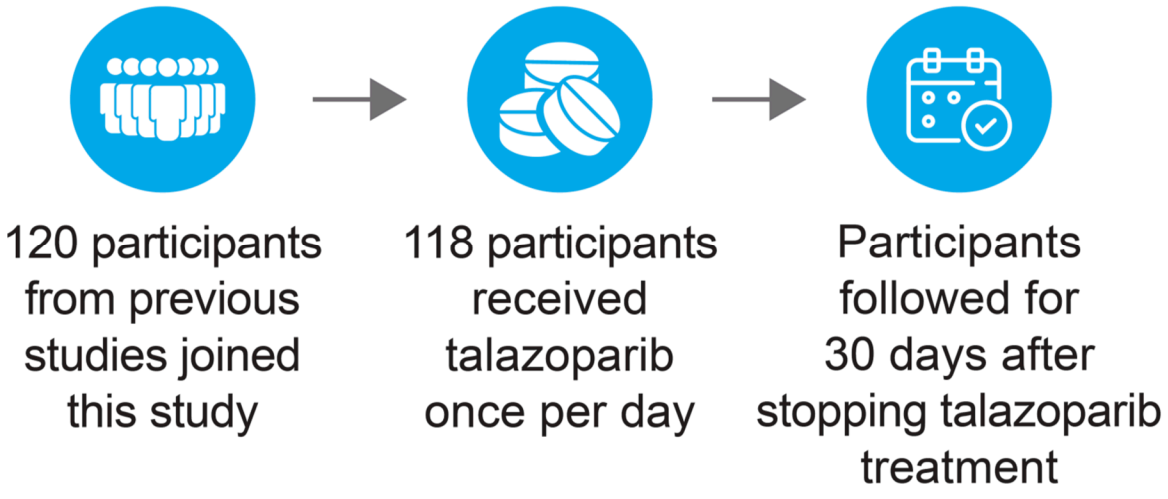
What happened during the study?

How was the study done?

Researchers studied a group of participants to learn more about the safety of talazoparib when used long term. Participants with advanced solid tumors who had previously completed a study of talazoparib were invited to join this study.

Participants received talazoparib once per day by mouth, and were monitored for any medical problems. The starting dose was up to 1 milligram (mg) per day, or the last dose they were able to tolerate in their previous study. Participants could continue receiving talazoparib as long as it continued to benefit them, and participants were followed up for 30 days after their last dose of talazoparib. This was an "open-label" study, which means that the participants and doctors knew which treatment and dose the participants received.

The figure below shows what happened during the study.



Where did this study take place?

The study was conducted at 24 locations in 9 countries in North America, Europe, and Central Asia.

When did this study take place?

It began 08 November 2016 and ended 20 July 2021.

Who participated in this study?

This study included adult men and women who had participated in a previous study of talazoparib in advanced solid tumors, and who were able to tolerate a dose of at least 0.25 milligrams (mg) per day.

- A total of 37 men (31%) participated
- A total of 83 women (69%) participated
- All participants were between the ages of 20 and 93 years

A total of 120 participants joined the study, and 118 participants (98%) received talazoparib. The reasons for stopping talazoparib treatment were:

- Medical problem: 10 participants (8%)
- Doctor decision: 5 participants (4%)
- Worsening cancer: 85 participants (71%)
- Participant decision: 6 participants (5%)
- Lost contact with participant: 1 participant (1%)
- Other reason: 11 participants (9%)

How long did the study last?

The amount of time that participants were in this study varied. The median (middle) amount of time that participants received talazoparib during this study was 3.7 months. The entire study took almost 5 years to complete.

When the study ended in July 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 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 the 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 110 out of 118 (93%) treated participants had at least 1 medical problem. Nine (8%) participants stopped taking talazoparib because of medical problems. The most common medical problems – those reported by at least 10% of participants – are described below.

Below are instructions for understanding 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 at least 10% of participants are listed.
- The **2nd** column tells how many of the 118 participants treated with talazoparib reported each medical problem. Next to this number is the percentage of the 118 participants treated with talazoparib who reported the medical problem.
- Using these instructions, you can see that for 39 out of the 118 (33%) participants treated with talazoparib, a low number of red blood cells was reported as a medical problem.

Table 1. Commonly reported medical problems by study participants	
Medical Problem	**Talazoparib (118 Participants)**
Low number of red blood cells	39 out of 118 participants (33%)
Nausea	29 out of 118 participants (25%)
Feeling tired	28 out of 118 participants (24%)
Trouble breathing	17 out of 118 participants (14%)
Low number of platelets in blood	17 out of 118 participants (14%)
Pain in the abdomen	16 out of 118 participants (14%)
Vomiting	16 out of 118 participants (14%)
Low appetite	14 out of 118 participants (12%)
Low number of a type of white blood cells	14 out of 118 participants (12%)
Weakness	12 out of 118 participants (10%)
Back pain	12 out of 118 participants (10%)

Diarrhea	12 out of 118 treated (10%)

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 45 out of 118 (38%) treated participants had serious medical problems. The most common serious medical problems – those reported by at least 2% of participants – are described below.

Below are instructions for understanding Table 2.

Instructions for Understanding Table 2.

- The **1st** column of Table 2 lists serious medical problems that were commonly reported during the study. All serious medical problems reported by at least 2% of participants are listed.
- The **2nd** column tells how many of the 118 participants treated with talazoparib reported each serious medical problem. Next to this number is the percentage of the 118 participants treated with talazoparib who reported the serious medical problem.
- Using these instructions, you can see that for 4 out of the 118 (3%) participants treated with talazoparib, a low number of red blood cells was reported as a serious medical problem.

Table 2. Commonly reported serious medical problems by study participants	
Serious Medical Problem	**Talazoparib (118 Participants)**
Low number of red blood cells	4 out of 118 participants (3%)
Worsening cancer	4 out of 118 participants (3%)
Trouble breathing	4 out of 118 participants (3%)
Cancer of the ovary	3 out of 118 participants (3%)

A total of 15 out of 118 (13%) treated participants died during this study. Worsening cancer was the most common cause of death. No deaths were considered by the study doctors to be related to talazoparib.

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 **NCT02921919**

www.clinicaltrialsregister.eu Use the study identifier **2016-001972-31**

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!