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:	Avelumab (MSB0010718C); Talazoparib (MDV3800, BMN 673)
Protocol Number:	B9991030
Dates of Study:	19 July 2018 to 22 December 2021
Title of this Study:	A study to Evaluate the Efficacy and Safety of Avelumab in Combination with Chemotherapy [A Randomized, Open-Label, Multicenter, Phase 3 Study to Evaluate the Efficacy and Safety of Avelumab in Combination with Chemotherapy Followed by Maintenance Therapy of Avelumab in Combination With the Poly (Adenosine Diphosphate [ADP]-Ribose) Polymerase (PARP) Inhibitor Talazoparib in Patients With Previously Untreated Advanced Ovarian Cancer (JAVELIN Ovarian PARP 100)]
Date(s) of this Report:	26 October 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 Ovarian Cancer?

Ovarian cancer is the leading cause of death among reproductive organ-related cancers in women. In advanced ovarian cancer, also called late-stage ovarian cancer, the cancer has spread outside the ovaries to other organs.

What is Avelumab?

Avelumab is a biologic agent that is approved for treatment of certain other cancers and is given to patients intravenously (by injection into vein). Avelumab is an investigational therapy which belongs to a group of drugs called immunotherapies. It works by stimulating the body's own defense (immune) system against cancer. It helps the body to fight cancer by interfering with the uncontrolled division of tumor cells.

What is Talazoparib?

Talazoparib is approved to treat other types of cancer but not approved for treatment of advanced ovarian cancer.

What was the purpose of this study?

The purpose of this study was to test if receiving avelumab combined with standard frontline platinum-based chemotherapy (the first treatment before and/or after surgery for ovarian cancer) followed by avelumab and talazoparib as so-called maintenance treatment (treatment given to help keep cancer from coming back after initial therapy), will help patients live longer without the disease getting worse compared to standard chemotherapy plus bevacizumab (another drug used to treat cancer) and maintenance with bevacizumab alone.

Researchers wanted to know:

Did the participants receiving avelumab along with standard chemotherapy followed by maintenance with avelumab and talazoparib live longer without the disease getting worse?

What happened during the study?

How was the study done?

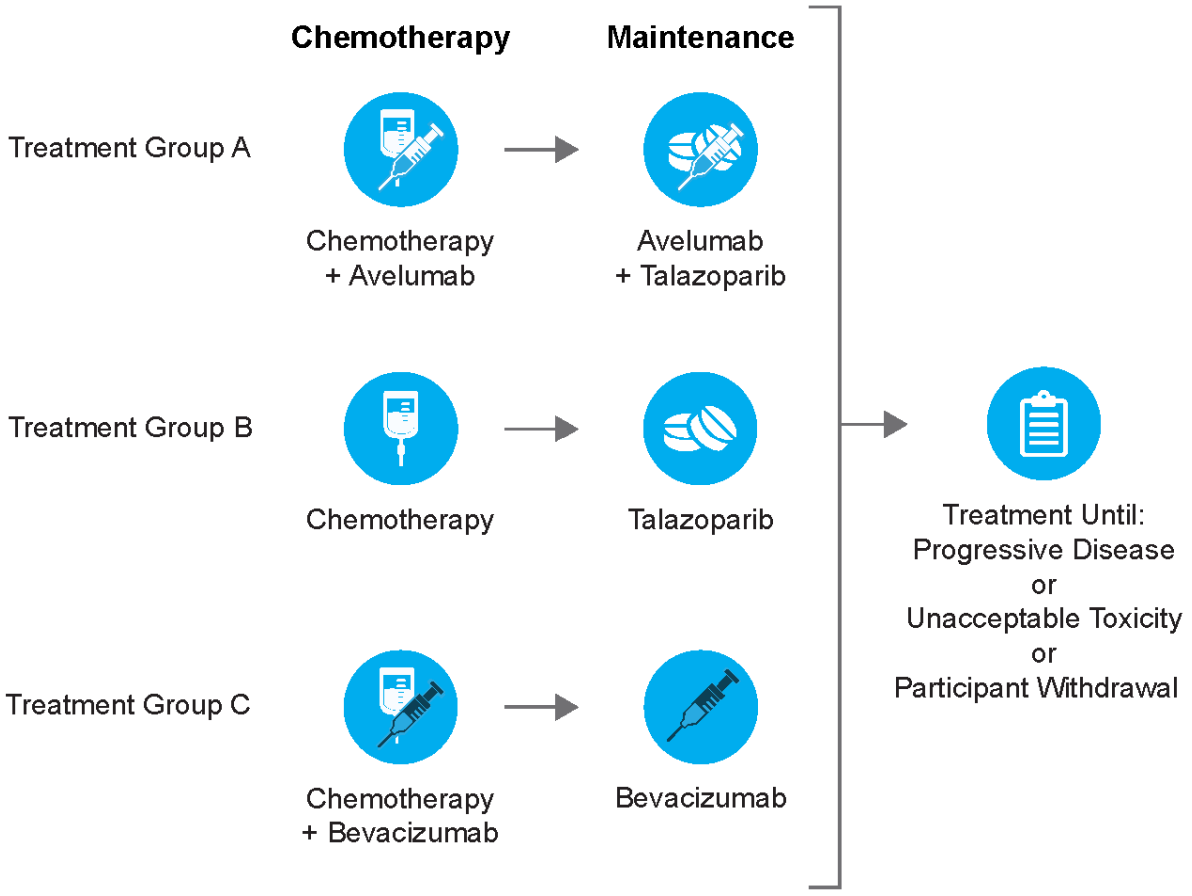
Following standard chemotherapy before and/or after primary surgery, researchers tested avelumab on a group of study participants to find out if adding avelumab to standard chemotherapy and maintenance treatment helped participants live longer without their cancer getting worse.

The study included 2 treatment periods, first the chemotherapy period and after that the maintenance period where 3 groups of participants were treated.

Combined carboplatin and paclitaxel were the standard chemotherapy drugs given to patients.

A diagram of the study design is shown below in Figure 1

Figure 1: What Happened During the Study?



This was an open-label study. This means that the study participants and the researchers knew what medications the participants were getting. Participants were assigned to each treatment by chance alone. This is known as a "randomized" study, and it helps make the treatments similar and more even to compare.

Where did this study take place?

The Sponsor ran this study at 30 locations in 10 countries around the world.

When did this study take place?

The study began on 19 July 2018 and ended on 22 December 2021.

Who participated in this study?

The study included women who were 18 years or older, who had confirmed advanced (so called late stage) ovarian cancer and who were not previously treated for their cancer.
Among 79 women patients enrolled in the study, a total of 76 patients received the study medications. Three (3) participants in Group A were not treated since the sponsors ended the study before they were treated. All participants were between the ages of 32 and 84.

Participants were to be treated until the disease became worse, or the medicine became too toxic for the participants.

Of the 79 participants who participated in the study, 54 finished chemotherapy phase of the study and 15 completed the maintenance therapy phase.

25 participants did not complete the chemotherapy because of:

- Unwanted reactions to the drugs
- Worsening of the disease
- Sponsor's decision to end treatment
- Participant's decision to withdraw
- Physician's decision

How long did the study last?

- The study was stopped early by the Sponsor. This was done because adding avelumab to treatment failed to show any benefit in another study in ovarian cancer (JAVELIN Ovarian 100, B9991010).

When the study ended in December 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 the study participants who took avelumab along with standard treatment live longer without their cancer getting worse?

Researchers were unable to measure whether the participants taking avelumab with standard treatment lived longer without their cancer getting worse compared to chemotherapy alone. Only a small number of participants (11% of what was planned) had time to join the study before the study was stopped for enrolment.

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 participants in this study had at least 1 medical problem. A total of 12 participants stopped taking at least one study medication because of medical problems. The most common medical problems, reported by more than 20% 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 20% of participants are listed.
- The 2nd column tells how many of the 29 participants in Group A (taking avelumab + carboplatin + paclitaxel during treatment period and avelumab + talazoparib during maintenance period) reported each medical problem. Next to this number is the percentage of the 29 participants in Group A who reported the medical problem.
- The 3rd column tells how many of the 13 participants in Group B (taking carboplatin + paclitaxel during treatment period and talazoparib during maintenance period) reported each medical problem. Next to this number is the percentage of the 13 participants in Group B who reported the medical problem.
- The 4th column tells how many of the 34 participants in Group C (taking carboplatin + paclitaxel + bevacizumab during treatment period and bevacizumab during maintenance period) reported each medical problem. Next to this number is the percentage of the 34 participants in Group C who reported the medical problem.
- Using these instructions, you can see that 14 out of the 29 (48%) participants taking avelumab + carboplatin + paclitaxel during treatment period and avelumab + talazoparib during maintenance period reported feeling tired.

Table 1. Commonly reported medical problems by study participants			
Medical Problem	**Group A (29 Participants)**	**Group B (13 Participants)**	**Group C (34 Participants)**
Feeling Tired	14 out of 29 participants (48%)	6 out of 13 participants (46%)	9 out of 34 participants (26%)
Hair Loss	12 out of 29 participants (41%)	7 out of 13 participants (54%)	10 out of 34 participants (29%)
Low red blood cell count	12 out of 29 participants (41%)	3 out of 13 participants (23%)	14 out of 34 participants (41%)
Nausea	12 out of 29 participants (41%)	4 out of 13 participants (31%)	14 out of 34 participants (41%)
Low white blood cell count	12 out of 29 participants (41%)	5 out of 13 participants (38%)	14 out of 34 participants (41%)
Joint Pain	11 out of 29 participants (38%)	4 out of 13 participants (31%)	11 out of 34 participants (32%)
Loose Stools	11 out of 29 participants (38%)	3 out of 13 participants (23%)	11 out of 34 participants (32%)
Constipation	9 out of 29 participants (31%)	2 out of 13 participants (15%)	12 out of 34 participants (35%)
Stomach Pain	8 out of 29 participants	3 out of 13 Participants	7 out of 34 Participants

	(28%)	(23%)	(21%)
Dizziness	8 out of 29 participants (28%)	4 out of 13 participants (31 %)	5 out of 34 participants (15%)
Muscle Pain	8 out of 29 participants (28%)	2 out of 13 participants (15%)	3 out of 34 participants (9%)
Nerve Injury Causing Numbness and Tingling	8 out of 29 participants (28%)	1 out of 13 participants (8%)	12 out of 34 participants (35%)
Low Blood Platelets	8 out of 29 participants (28%)	0 out of 13 participants (0 %)	2 out of 34 participants (6%)
Shortness of Breath	7 out of 29 participants (24%)	3 out of 13 participants (23%)	5 out of 34 participants (15%)
Cough	6 out of 29 participants (21%)	3 out of 13 participants (23%)	5 out of 34 participants (15%)
Headache	5 out of 29 participants (17%)	2 out of 13 participants (15%)	10 out of 34 participants (29%)
Infection of the Kidneys, Bladder, or Urethra	4 out of 29 participants (14%)	2 out of 13 participants (15%)	7 out of 34 participants (21%)
Vomiting	4 out of 29 participants (14%)	4 out of 13 participants (31 %)	7 out of 34 participants (21%)

Nerve injury Causing Numbness, Tingling, and Weakness	3 out of 29 participants (10%)	3 out of 13 participants (23 %)	3 out of 34 participants (9%)
Weakness	2 out of 29 participants 7%	3 out of 13 participants (23%)	3 out of 34 participants 9%
White Blood Cell (Neutrophil) Count Decreased	2 out of 29 participants (7%)	3 out of 13 participants (23%)	3 out of 34 participants (9%)
High Blood Pressure	0 out of 29 participants (0%)	1 out of 13 participants (8%)	11 out of 34 participants (32%)
High levels of protein in urine	0 out of 29 participants (0%)	0 out of 13 participants (0%)	11 out of 34 participants (32%)

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 28 participants in the whole study had at least one serious medical problem.

9 participants in the Avelumab group had at least one serious medical problem. 2 participants reported serious low white blood cell count with fever.

4 participants in the standard chemotherapy group had had at least one serious medical problem. Nausea and vomiting were reported by 2 participants.

15 participants in the chemotherapy + bevacizumab group had at least one serious medical problem. 3 participants reported serious low white blood cell count with fever.

- 4 participants passed away during the study due to their cancer getting worse. Researchers do not believe any of the deaths were related to study medications

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 NCT03642132
www.clinicaltrialsregister.eu	Use the study identifier 2017-004456-30
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number B9991030

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 patients, and you helped us to do that!