This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to learn about the effect of niraparib combined with bevacizumab in delaying the growth or return of cancer or death in participants with advanced ovarian cancer who responded to platinum-based chemotherapy in addition to bevacizumab.

Full Scientific Title: A phase 2, single-arm, open-label study to evaluate the safety and efficacy of niraparib combined with bevacizumab as maintenance treatment in patients with advanced ovarian cancer, fallopian tube cancer, or primary peritoneal cancer following front-line platinum-based chemotherapy with bevacizumab.

Study Number: 213358 (3000-02-004)

Who sponsored this study?

Tesaro, a GlaxoSmithKline (GSK) company
GSK Clinical Support Help Desk
Website: clinicalsupporthd.gsk.com/contact.html
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When and where was this study done?

The study started in December 2017. When this summary was finalised, enrolment was closed but the study was ongoing. Data collected up to December 2020 are included in this summary. This is called the data cut-off. All study sites were in the United States.

What was the main objective of this study?

Ovarian cancer starts in the ovaries, fallopian tubes, or peritoneum. Advanced ovarian cancer is a cancer that has spread to other organs of the body.

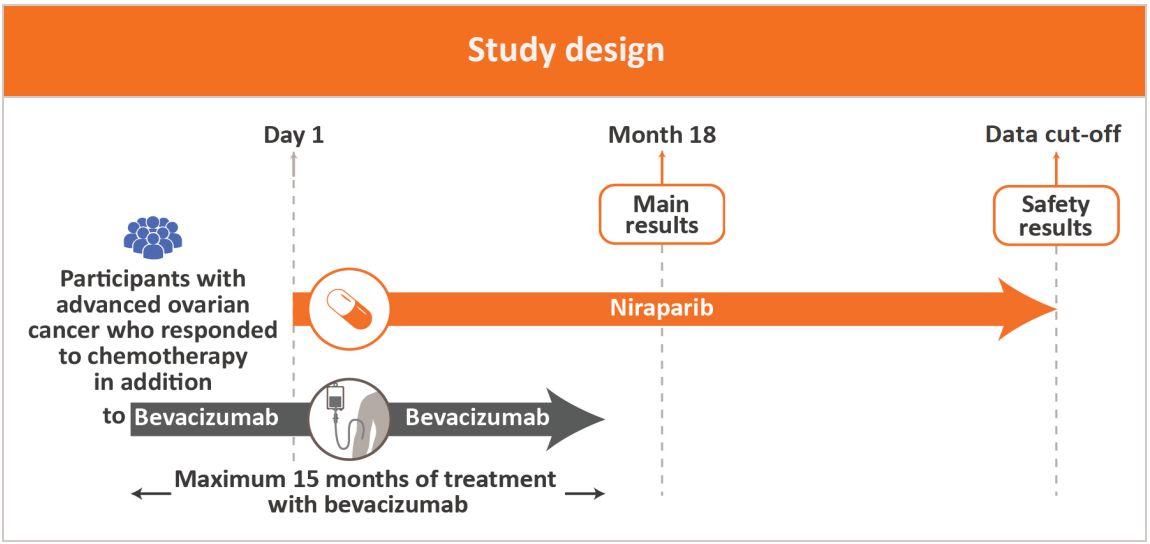
Niraparib is a medicine that can cause cancer cells as well as some healthy cells to die. It may slow down the growth or return of cancer. Bevacizumab is a medicine that is often used with other medicines to increase their effects in treating cancers.

Patients with advanced ovarian cancer who responded to platinum-based chemotherapy in addition to bevacizumab (had partial or complete tumour shrinkage) took part in this study.

Researchers wanted a better understanding of how niraparib combined with bevacizumab can be used to delay the growth or return of the cancer (disease progression) or death of these participants at Month 18. Researchers also studied the safety of niraparib and bevacizumab.

Which medicines were studied?

As shown in the figure below, participants received niraparib once daily for up to three years. They also continued receiving bevacizumab once every three weeks for at least ten months.



Participants could continue in the study for up to three years or until their disease progressed or the participant died. Participants with no disease progression up to the data cut-off could continue treatment with niraparib.

Which participants took part in this study?

Studies have a list of requirements for participants who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Women with advanced (stage III or IV) ovarian cancer were included in the study if they:

- Were at least 18 years old.
- Had a tumour removal surgery.
- Had begun their last cycle of platinum-based chemotherapy within 12 weeks of Day 1.
- Had partial or complete response to platinum-based chemotherapy.
- Received bevacizumab for at least three months before starting the study.
- Had tumour tissue samples (biopsy) or were willing to undergo a fresh biopsy before Day 1.

Women were excluded from the study if they had:

- Specific, less-common types of ovarian cancer as assessed by the study doctor.
- Problems related to the heart, stomach, and/or intestine.
- Higher than normal levels of protein in their urine on Day 1.
- Received a medicine similar to niraparib before starting the study.
- Any other disease(s) or taken any medicine(s) that the study doctor thought would affect the results of the study.

Overall, 105 women received at least one dose of the study medicine(s). The average age was 60 years. The youngest participant was 37 years old and the oldest participant was 82 years old.

For more detailed information about the participants included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

What were the main results of the study?

Study doctors assessed each participant's cancer using imaging, physical exams, and blood tests. They recorded if the participant's disease progressed or if the participant died.

At Month 18, 62% of participants were alive with no disease progression.

More information about the study results is available in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summary (a link to the summary is provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicine(s). The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine(s).

The side effects in this summary have been reported from Day 1 to the data cut-off.

Serious side effects

Nineteen participants (18%) died, but none due to side effects. Serious side effects were reported by 21 participants (20%). The table below shows the number of participants (percent) with serious side effects that were reported by 2% or more of participants.

Number of participants (percent) with serious side effects reported by 2% or more of participants	
	Study medicine(s) **105 participants**
Lower than normal levels of platelets	8 (8%)
Very low levels of platelets	6 (6%)
High blood pressure	2 (2%)

Non-serious side effects

Non-serious side effects were reported by all 105 participants (100%). The table below shows the number of participants (percent) with non-serious side effects that were reported by 20% or more of participants.

Number of participants (percent) with non-serious side effects reported by 20% or more of participants	
	Study medicine(s) **105 participants**
Tiredness	60 (57%)
Nausea	55 (52%)
Very low levels of haemoglobin	52 (50%)
High blood pressure	50 (48%)
Lower than normal levels of platelets	42 (40%)
Higher than normal levels of protein in urine	41 (39%)
Very low levels of platelets	36 (34%)
Headache	32 (30%)

How has this study helped participants and researchers?

Participants with advanced ovarian cancer who responded to platinum-based chemotherapy in addition to bevacizumab took part in this study. Study results provided a better understanding of how niraparib combined with bevacizumab can be used to delay disease progression. The side effects reported in this study were as expected.

Are there plans for further studies?

Other studies of niraparib in participants with ovarian cancer have been conducted and some are ongoing or planned.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study number associated with this study is shown below with an internet link to the scientific summary.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events. When the study is complete, final results will be available in the scientific summaries.

Organisation and Website	Study Number
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03326193[1]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the participants who contributed to this study. The results of this study will help answer scientific questions about treating patients with ovarian cancer.

The content for this document was finalised by GSK on 10 November 2021. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/study/NCT03326193