This document provides a short summary of this study for a general audience. You can find more information in the scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study names

Short Title: A study to see how well niraparib works, in delaying the growth or return of cancer or death, in patients with advanced ovarian cancer who responded to their first chemotherapy.

Full Scientific Title: A phase 3, randomised, double-blind, placebo-controlled, multicentre study of niraparib maintenance treatment in patients with advanced ovarian cancer following response on front-line platinum-based chemotherapy.

Study Number: PR-30-5017-C (213359)

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 was this study done?

The study started in July 2016. Enrolment was closed, but the study was ongoing when this summary was finalised. Data collected up to May 2019 are included in this summary. This is called the data cut-off.

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 cells to die. This may slow down the growth or return of the cancer.

Patients with advanced ovarian cancer who responded to chemotherapy (had partial or complete tumour shrinkage) took part in this study. Researchers wanted to see how well niraparib delays the growth or return of the cancer by measuring the progression-free survival in these patients. Progression-free survival is the time until the cancer grows or returns or the patient dies. Researchers also studied the safety of niraparib.

Which medicines were studied?

On Day 1, patients were placed in one of the following two treatment groups by chance (randomisation):

- Niraparib
- Placebo (no active medicine)

Twice as many patients received niraparib compared with placebo. Neither the patients nor the study doctors knew who was receiving which treatment. This is called a double-blind study.

Patients visited the clinic once every four weeks and could continue in the study for up to seven years or until their cancer had grown or returned or the patient died.

Which patients took part in this study?

Studies have a list of requirements for patients 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 begun their last cycle of chemotherapy within 12 weeks of Day 1.
- Had partial or complete response to platinum-type chemotherapy.
- Met specific surgical criteria based on the stage of cancer.
- 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.
- More than two tumour removal surgeries.
- Abnormal blood test results for more than a month after chemotherapy.
- 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.

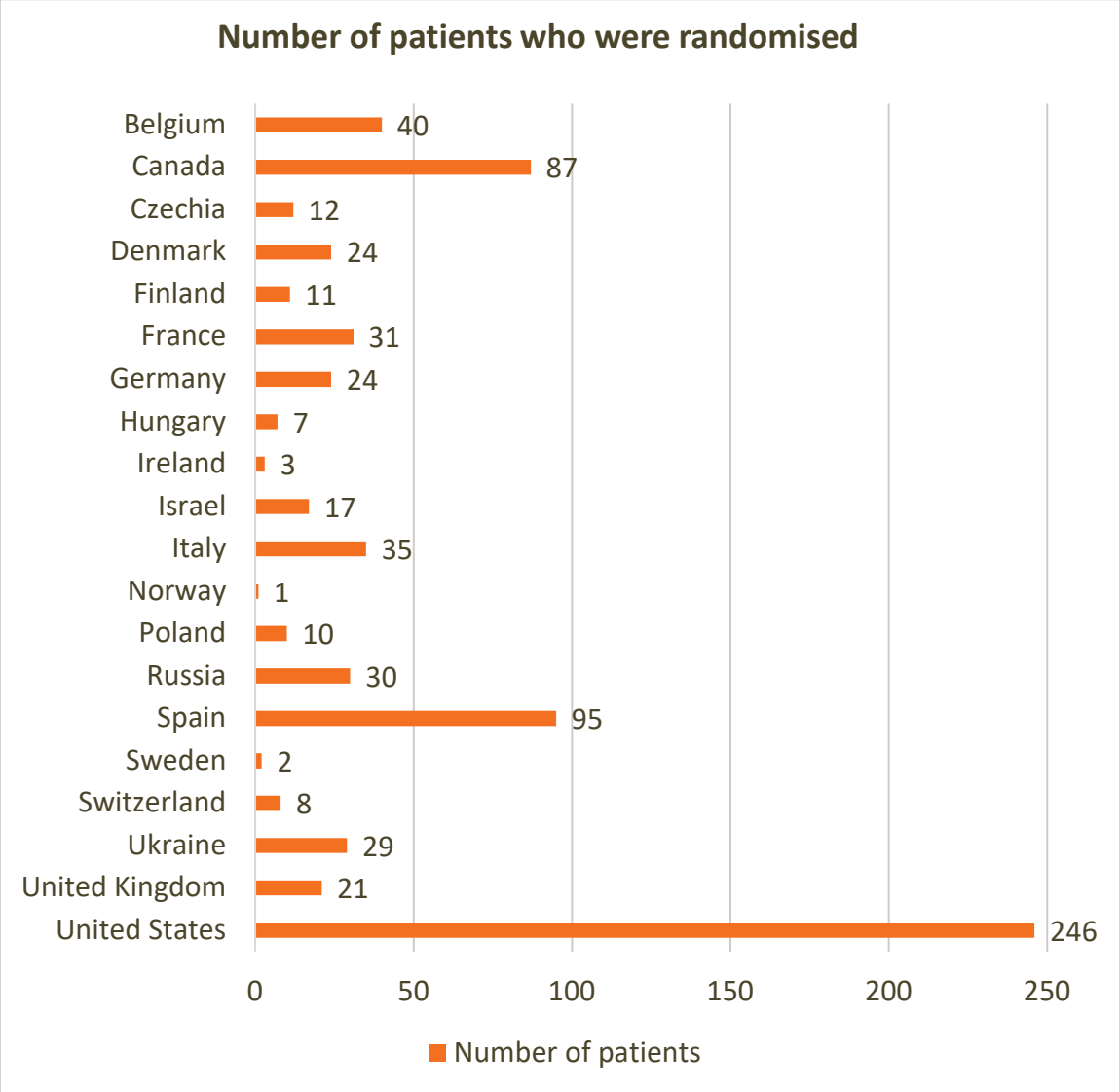
Overall, 733 women were randomised. The average age was 61 years. The youngest patient was 32 years old and the oldest patient was 88 years old.

At the data cut-off, 387 patients had died or their cancer had grown or returned.

For more detailed information about the patients included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

Where was this study done?

Study sites were in 20 countries.

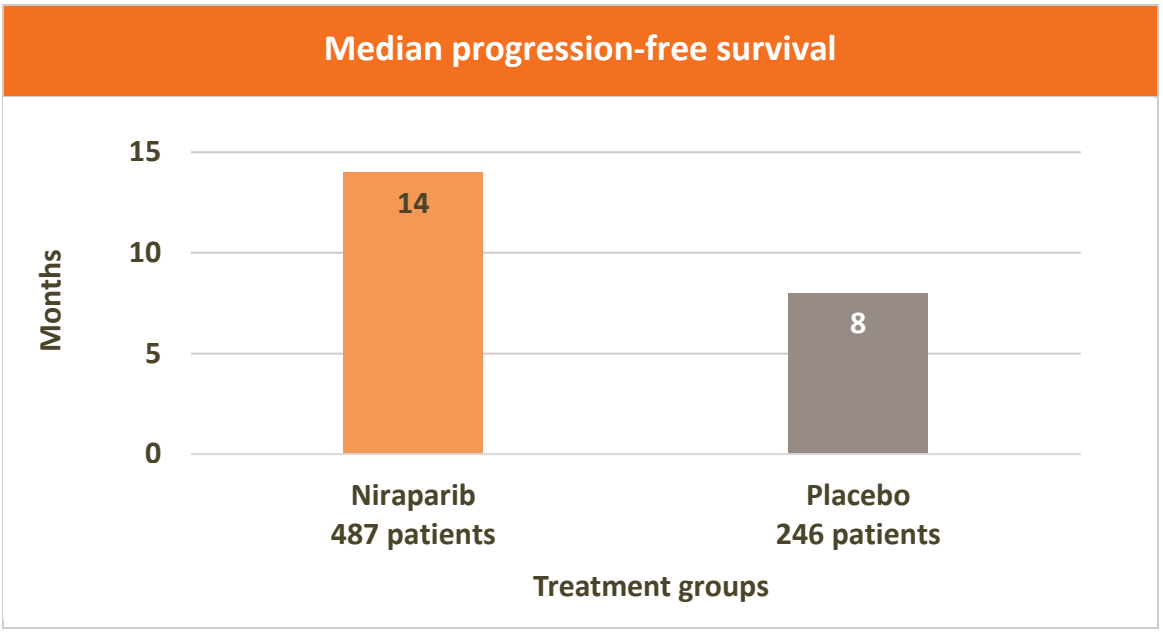


What were the main results of the study?

Study doctors assessed each patient's cancer using imaging, physical exams, and blood tests. Study doctors measured progression-free survival by recording the time in months from Day 1 until the cancer had grown or returned or the patient died.

The median progression-free survival was calculated for each treatment group at the data cut-off.

Results are shown in the figure below.



These results showed that niraparib provided about a six month longer progression-free survival compared with placebo. This means that there was a 38% reduced risk of cancer growth or return or patient death with niraparib treatment.

More information about the study results is available in the scientific results summaries (links to those summaries are 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 summaries (links to those summaries are 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. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine.

In blinded studies, the doctor does not know which study medicine the patient is taking. In some cases, side effects will be assigned to placebo.

A total of 728 patients (484 patients in the niraparib group and 244 patients in the placebo group) received at least one dose of study medicine. Side effects were reported for these patients.

Serious side effects

Serious side effects were reported by 118 patients (24%) in the niraparib group and 6 patients (2%) in the placebo group. The table below shows the number of patients (percent) with serious side effects that were reported by 1% or more of patients.

Number of patients (percent) with serious side effects reported by 1% or more of patients		
	Niraparib 484 patients	**Placebo 244 patients**
Very low levels of platelets	59 (12%)	0
Very low levels of haemoglobin	26 (5%)	0
Lower than normal levels of platelets	20 (4%)	0
Very low levels of neutrophils (a type of white blood cell)	6 (1%)	0
Overdose	4 (less than 1%)	3 (1%)

Non-serious side effects

Non-serious side effects were reported by 463 patients (96%) in the niraparib group and 167 patients (68%) in the placebo group. The table below shows the number of patients (percent) with non-serious side effects that were reported by 20% or more of patients.

Number of patients (percent) with non-serious side effects reported by 20% or more of patients		
	Niraparib 484 patients	**Placebo 244 patients**
Very low levels of haemoglobin	291 (60%)	31 (13%)
Nausea	245 (51%)	49 (20%)
Very low levels of platelets	207 (43%)	8 (3%)
Tiredness	144 (30%)	56 (23%)
Lower than normal levels of platelets	126 (26%)	3 (1%)
Constipation	125 (26%)	14 (6%)
Very low levels of neutrophils	124 (26%)	14 (6%)

How has this study helped patients and researchers?

Patients with advanced ovarian cancer who responded to previous chemotherapy took part in this study. Researchers concluded that niraparib reduced the risk of cancer growth or return or death compared with placebo. The side effects reported in this study were as expected.

Are there plans for further studies?

Other studies of niraparib in patients 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 numbers associated with this study are shown below with internet links to scientific summaries.

The scientific summaries include 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
European Medicines Agency (www.clinicaltrialsregister.eu)	2015-000952-11[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT02655016[2]

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.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-000952-11

[2] https://clinicaltrials.gov/ct2/show/study/NCT02655016

We would like to thank the patients 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 23 June 2021. The information in this summary does not include additional information available after this date.