

# Summary of Clinical Trial Results

For Laypersons



**A study to learn how effective and safe a medicine containing veliparib in combination with paclitaxel and carboplatin is compared to study doctor's choice of chemotherapy to treat adult patients with a certain type of advanced lung cancer**

## Overall Summary

- Researchers are looking for a better way to treat a certain type of lung cancer: advanced or metastatic non-squamous non-small cell lung cancer.
- In this study, study doctors (investigators) wanted to know whether patients with this type of lung cancer live longer when taking an experimental drug called veliparib, taken with the standard chemotherapy drugs carboplatin and paclitaxel in comparison to study doctor's choice of standard chemotherapy.
- This study took place from September 2014 to February 2020 in 20 countries.
- A total of 595 adults with advanced or metastatic non-squamous non-small cell lung cancer took part in this study, and 80 of these patients had tumors positive for a biomarker called LSP.
- The study was divided into 4 parts: the Screening Period, Treatment Period, Maintenance Period, and Survival Follow-Up.
- Overall survival in all of the patients was comparable among patients who received veliparib and carboplatin/paclitaxel to those seen in treatment with doctor's choice standard chemotherapy. LSP+ patients did not show significant improvement in overall survival when they received veliparib and carboplatin/paclitaxel (11.2 months) compared to patients who received doctor's choice standard chemotherapy (9.2 months).
- Overall side effects seen in treatment with veliparib taken in combination with carboplatin and paclitaxel were comparable to those seen in treatment with doctor's choice standard chemotherapy.
- The results of the study may be used by researchers to further develop this medicine.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

# 1. General information about the study

## 1.1. Why was the study done?



Researchers are looking for a better way to treat advanced and metastatic non-squamous non-small cell lung cancer. Non-small cell lung cancer is a form of lung cancer and accounts for more than 85% of all lung cancer cases.

- **Non-Squamous** is a certain subset of non-small cell lung cancer.
- **Advanced cancer** means it has spread to surrounding tissues.
- **Metastatic cancer** means it has spread to a different part of the body from where it started (in this case, from the lungs).

Doctors suggest chemotherapy (use of medicines to destroy cancer cells) as a standard of care to treat advanced or metastatic non-squamous non-small cell lung cancer. Researchers in this study wanted to

know whether an experimental drug called veliparib, in combination with standard chemotherapy drugs carboplatin (a platinum-based drug) and paclitaxel, could help treat this type of lung cancer better than standard platinum-based chemotherapy.

Veliparib stops certain proteins in the body that help cancer cells overcome damage to these cancer cells caused by radiation and anti-cancer drugs. Veliparib blocks these proteins, preventing cancer cells from repairing themselves to help make cancer treatments more effective.

The doctors in this study treated adult patients who were diagnosed with metastatic or advanced non-squamous non-small cell lung cancer but were not previously treated with chemotherapy. Researchers planned this study as a Phase 3, open-label, randomized study.

- **Phase 3 studies** test potential new treatments in a large number of patients with a condition or disease. In this Phase 3 study, the study doctors looked at the benefits of veliparib with chemotherapy versus doctor's choice standard chemotherapy in patients. The study doctors also looked for any side effects patients may have had after treatment with the study drug. Side effects are medical events considered by the study doctors to be at least possibly related to study drug/treatment.
- This study was "**open-label**", which means that both patients and study doctors knew which medicine/treatment was given to patients.
- This study was also **randomized**, which means a computer program was used to randomly (by chance) put the patients into 1 of 2 groups. This process is called "randomization", which helps make the groups equal and reduces the differences between the groups. Randomization allows the results of each treatment to be compared as accurately as possible.

## 1.1. Why was the study done? (continued)

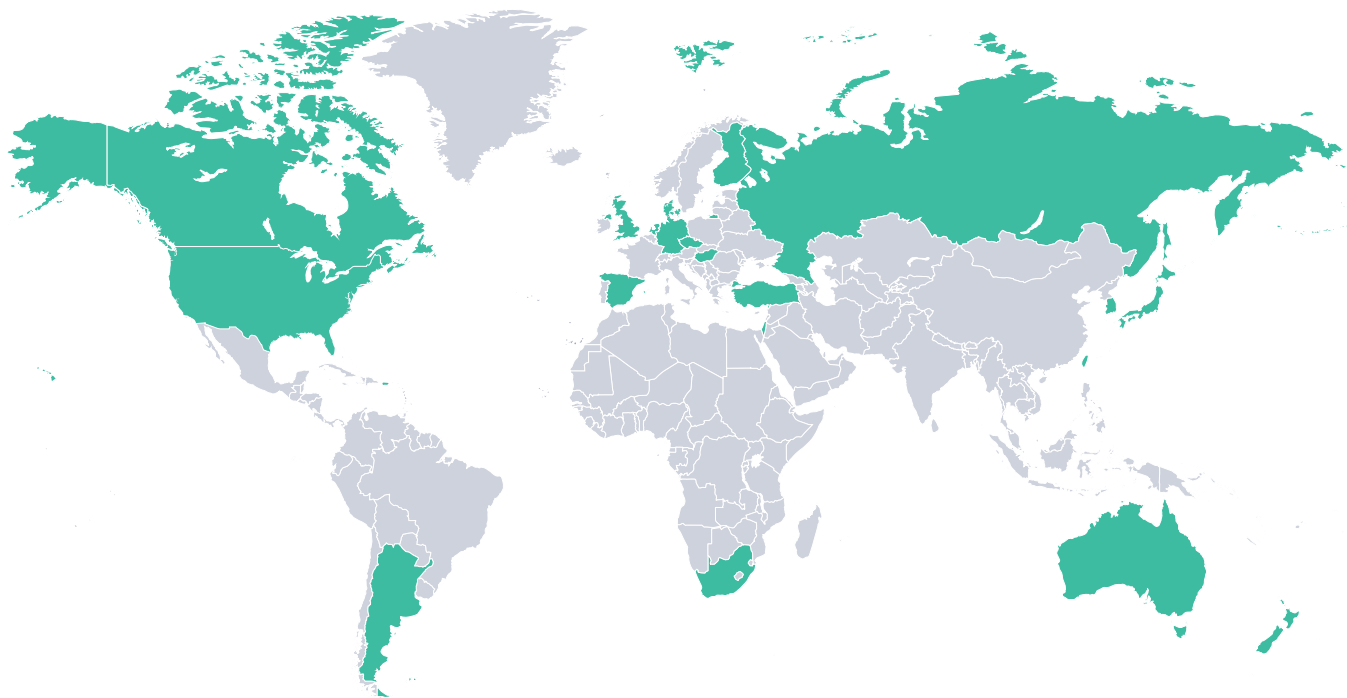
The main aim of the study was to find out whether:

- The overall survival (how long patients lived) in a subset of study patients (patients with tumors positive for the lung subtype panel [LSP] biomarker) improved after the addition of veliparib to carboplatin and paclitaxel in comparison to doctor's choice standard chemotherapy.
- The study also measured overall survival in all of the patients, no matter their LSP status.
- The study doctors also looked for any side effects patients may have had after treatment with the study drugs.

This summary only includes the results of this study, which may be different from the results of other studies.

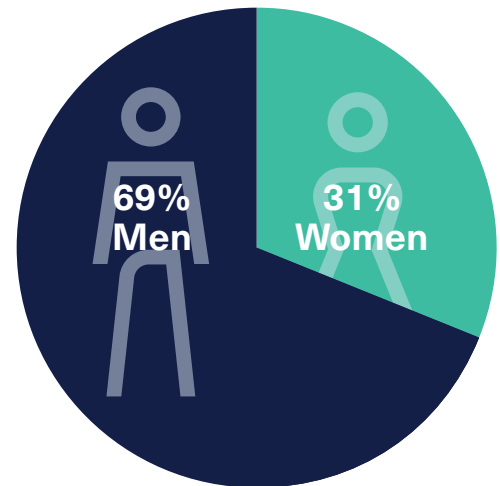
## 1.2. When and where did the study take place?

This study took place from September 2014 to February 2020 in the following countries: Argentina, Australia, Canada, Czech Republic, Denmark, Finland, Germany, Hungary, Israel, Japan, Republic of Korea, Netherlands, New Zealand, Russian Federation, South Africa, Spain, Taiwan, Turkey, United Kingdom, and United States.



## 2. What patients were included in this study?

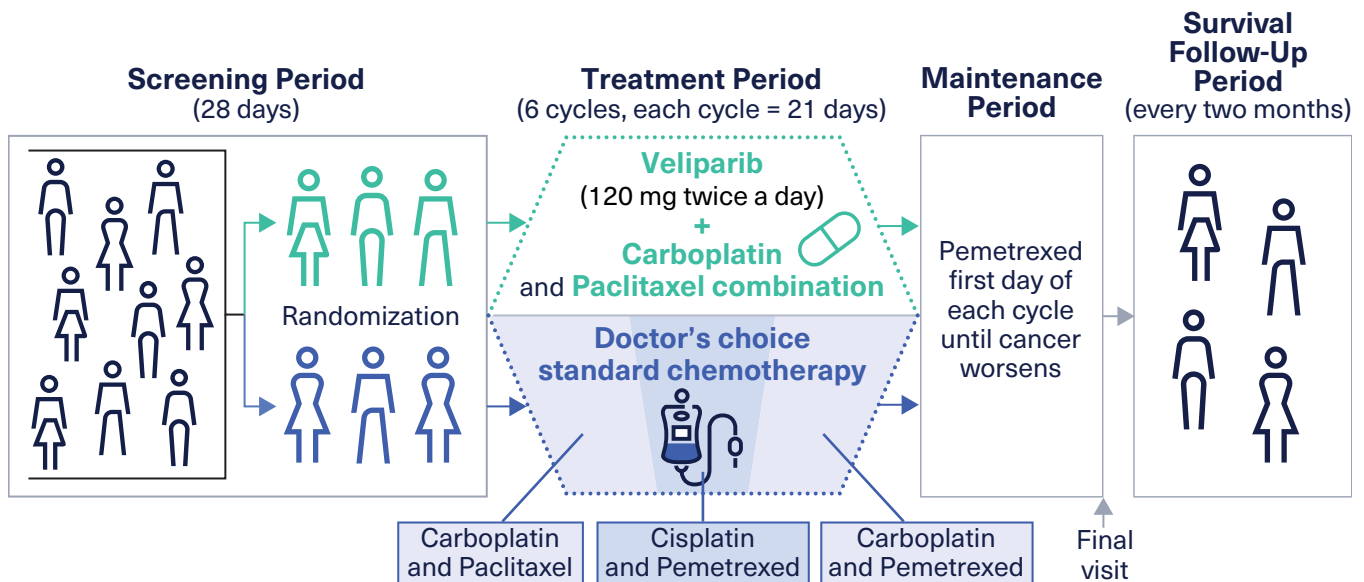
A total of 595 adult patients took part in the study, of whom 519 left the study or passed away and 76 did not. More men (69%) than women (31%) participated in the study. Patients ranged from 27 to 85 years of age, with an average age of 63 years. Approximately half of all patients (51%) were current smokers and the other half were former smokers (49%). Study doctors selected only adults to participate in this study. Patients either had metastatic disease or locally advanced disease that was untreatable by surgery or radiation. A total of 80 patients had tumors positive for the biomarker LSP. Patients must not have had chemotherapy treatment for advanced non-small cell lung cancer before this study.



In 2019, it was estimated that only 1 in 5 patients in the United States will survive five years following the diagnosis of lung cancer. This study followed patients until they left the study or passed away. Most patients experienced natural disease progression or passed away.

## 3. Which medicines were studied?

The medicine in this study was veliparib taken with carboplatin and paclitaxel, or doctor's choice standard chemotherapy that consisted of 3 different possible treatment combinations: carboplatin and paclitaxel; cisplatin and pemetrexed; or carboplatin and pemetrexed. The diagram below shows how the study was organized.



The study was divided into 4 periods:

- **Screening Period** – Before the study started, the Screening Period took place to check if patients could join the study. Once the patients were screened, a computer program was used to randomly (by chance) put patients into 1 of 2 treatment groups (veliparib with carboplatin and paclitaxel combination or doctor's choice standard chemotherapy). Both patients and study doctors knew which treatment was given to patients.
- **Treatment Period** (each Cycle = 21 days) – In the Treatment Period, patients assigned to veliparib and carboplatin + paclitaxel treatment group took capsules of veliparib by mouth twice a day for 7 days of each 3-week treatment cycle in combination with carboplatin/paclitaxel. Carboplatin and paclitaxel were given to patients through intravenous (IV) infusion (vein injection) on the first day of each treatment cycle. Patients assigned to doctor's choice standard chemotherapy received one of the three combinations (selected for each patient by their study doctor): carboplatin + paclitaxel, cisplatin + pemetrexed, or carboplatin + pemetrexed on the first day of each treatment cycle. These medicines were given to patients through IV infusion. In both treatment groups, the patients received these treatments for up to 6 cycles of treatment.
- **Maintenance Period** – After the Treatment Period, patients in both treatment arms continued on to maintenance therapy (if their study doctor thought it was appropriate), in which case they were given pemetrexed on the first day of each 3-week treatment cycle through IV infusion. Patients kept receiving pemetrexed until their cancer progressed.
- **Survival Follow-Up Period** – After a final visit (usually when the patient's cancer worsened or if the patient stopped treatment), patients were called by study doctors for survival follow-up once every 2 months (to measure how long each patient lived) until death.

## 4. What were the side effects?

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to the study treatment (veliparib, carboplatin, or paclitaxel in the veliparib arm, or doctor's choice standard chemotherapy).

- The total number of patients in the veliparib arm that had serious side effects was 20.8% of patients (61 patients). The total number of patients who received doctor's choice standard chemotherapy that had serious side effects was 17.4% of patients (50 patients).
- A total of 15.0% of patients (44 patients) in the veliparib arm stopped taking their study treatment because of side effects. A total of 13.2% of patients (38 patients) stopped taking doctor's choice standard chemotherapy because of side effects.
- A total of 1.7% of patients (5 patients) in the veliparib arm died during the study due to side effects. A total of 0.7% of patients (2 patients) in the doctor's choice standard chemotherapy group died during the study due to side effects.

The table on the following page shows information about the serious side effects patients had in the study (in 8 or more patients), as well as side effects patients had that led to the patient stopping the study drug, and side effects leading to death.

Overall Study		
	Veliparib + Carboplatin/ Paclitaxel (293 Patients)	Study Doctor's Choice Standard Chemotherapy (288 Patients)
Number of patients with serious side effects	61 (20.8% of patients)	50 (17.4% of patients)
Serious side effects in 8 or more patients		
• Fever with low white blood cell count	13 (4.4%)	7 (2.4%)
• Low red blood cell count	6 (2.0%)	14 (4.9%)
Number of patients who stopped taking study drug because of side effects	44 (15.0%)	38 (13.2%)
Reasons for stopping	Low red blood cell count, low white blood cell count, low platelet count, fever with low white blood cell count, abnormally fast heart rate, heart failure, nausea, abdominal pain, vomiting, discomfort, deterioration of health, sudden death, abnormal liver function, drug hypersensitivity, severe allergic reaction, low white blood cell count with infection, lung infection, nerve damage outside spinal cord and brain, cognitive disorder, disturbance of the senses, low blood pressure	Low red blood cell count, low white blood cell count, low platelet count, fever with low white blood cell count, ear poisoning, excessive tearing, nausea, vomiting, constipation, diarrhea, tiredness, discomfort, weakness, drug hypersensitivity, wound, increase of blood creatinine, nerve damage outside of the spinal cord and brain, change in sense of taste, nerve damage, kidney disorder, kidney failure, low blood pressure when standing, decreased appetite
Number of side effects leading to death	5 (1.7%)	2 (0.7%)
Side effect(s)	Heart failure, reduced blood flow to colon, sudden death, heart injury	Multiple organ dysfunction and sudden death

About 91.5% of patients (268 patients) in the veliparib arm and 88.5% of patients (255 patients) who received doctor's choice standard chemotherapy had side effects during the study.

The table on the following page shows information about the common side effects (in at least 20% or more patients in either treatment group) in this study. The most common side effect was hair loss.

Overall Study		
	Veliparib + Carboplatin/ Paclitaxel (293 Patients)	Study Doctor's Choice Standard Chemotherapy (288 Patients)
Number of patients with at least one side effect	268 (91.5% of patients)	255 (88.5% of patients)
• Hair loss	136 (46.4%)	32 (11.1%)
• Nerve damage outside of the spinal cord and brain	131 (44.7%)	37 (12.8%)
• Low red blood cell count	104 (35.5%)	110 (38.2%)
• Low white blood cell count	109 (37.2%)	91 (31.6%)
• Nausea	80 (27.3%)	123 (42.7%)
• Tiredness	70 (23.9%)	84 (29.2%)
• Decreased appetite	54 (18.4%)	74 (25.7%)
• Vomiting	38 (13.0%)	63 (21.9%)
• Low platelet count	76 (25.9%)	58 (20.1%)

Across the whole study, both the treatment groups (veliparib and carboplatin/paclitaxel combination, and doctor's choice standard chemotherapy) showed similar side effects. Also, side effects were similar in LSP+ patients compared to the overall patient population.

## 5. What were the overall results of the study?

The study was completed as planned. LSP positive patients did not show significant improvement in overall survival when they received veliparib and carboplatin/paclitaxel (11.2 months) compared to patients who received doctor's choice standard chemotherapy (9.2 months). Overall survival in all of the patients was comparable among patients who received veliparib and carboplatin/paclitaxel to those seen in treatment with doctor's choice standard chemotherapy. Overall side effects seen in treatment with veliparib taken in combination with carboplatin and paclitaxel were comparable to those seen in treatment with doctor's choice standard chemotherapy. Side effects in this patient population were similar to side effects seen with the chemotherapy drugs used in other previous studies.

## 6. How has the study helped patients and researchers?

The results of this study found no significant benefit of treatment with veliparib in combination with carboplatin/paclitaxel compared to doctor's choice standard chemotherapy. This study also learned that veliparib is well tolerated when added to treatment with chemotherapy.

This summary only shows the results of this study, which may be different from the results of other studies. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.



## 7. Are there any plans for future studies?

Studies of veliparib in other types of cancer are currently ongoing.

## 8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.

## 9. Where can I find out more information about this study?

Title of Study	A Randomized, Open-Label, Multicenter, Phase 3, Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy in Subjects Receiving First Cytotoxic Chemotherapy for Metastatic or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) and Who Are Current or Former Smokers
Protocol Number	M14-359
Clinicaltrials.gov	NCT02264990 <a href="https://clinicaltrials.gov/ct2/show/NCT02264990">https://clinicaltrials.gov/ct2/show/NCT02264990</a>
EudraCT	2014-002565-30 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-002565-30">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-002565-30</a>
Study Sponsor	AbbVie Inc. Phone: (800) 633-9110 Email: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

## Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

