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Summary of Clinical Trial Results

For Laypersons

A study to learn the safety and effectiveness of rovalpituzumab tesirine (Rova-T) in patients who have advanced small cell lung cancer when Rova-T is used immediately after patients have completed taking chemotherapy

Overall Summary

- Researchers are looking for a better way to treat advanced small cell lung cancer that has spread throughout the body (advanced).
- Researchers in this study wanted to know whether a new drug called rovalpituzumab tesirine (Rova-T), given after completion of chemotherapy in addition to standard treatment chemotherapy, could help treat this type of lung cancer.
- This study took place from February 2017 to November 2019 in 41 countries.
- A total of 748 adults with small cell lung cancer took part in this study.
- Patients were divided into two groups after completion of chemotherapy. One group received Rova-T and the other group received a placebo (no real medicine).
- The results of this study showed that there was no improvement in overall survival for patients who received rovalpituzumab tesirine (Rova-T) compared to placebo. However, the average length of time before disease progression was longer for patients who received Rova-T compared to patients who received placebo.
- Overall, there was a higher number of side effects in patients who received Rova-T compared to patients who received placebo.
- As no survival benefit was found among patients who received Rova-T compared to placebo, this study was ended early.
- Findings from this study may be used in other studies with similar patient populations. 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 What was the main objective of this study?

Researchers are looking for a better way to treat small cell lung cancer.

- Small cell lung cancer is an aggressive form of lung cancer which accounts for 15 - 20% of all types of lung cancer.
- Advanced stage lung cancer means the cancer has spread to a different part of the body from where it started (in this case, from the lungs).

Although many patients' cancer improves with their first treatment, the cancer often comes back quickly or spreads. Therefore, researchers in this study wanted to know whether a new drug called rovalpituzumab tesirine (Rova-T), given after chemotherapy treatment is completed, could help patients with small cell lung cancer.

Rova-T is a type of drug called an antibody drug conjugate (ADC). ADCs usually have 2 parts: a part that targets tumor cells (the antibody) and a cell-killing part (the toxin). Antibodies are proteins that are part of our immune system. They can stick to and attack specific targets on cells.

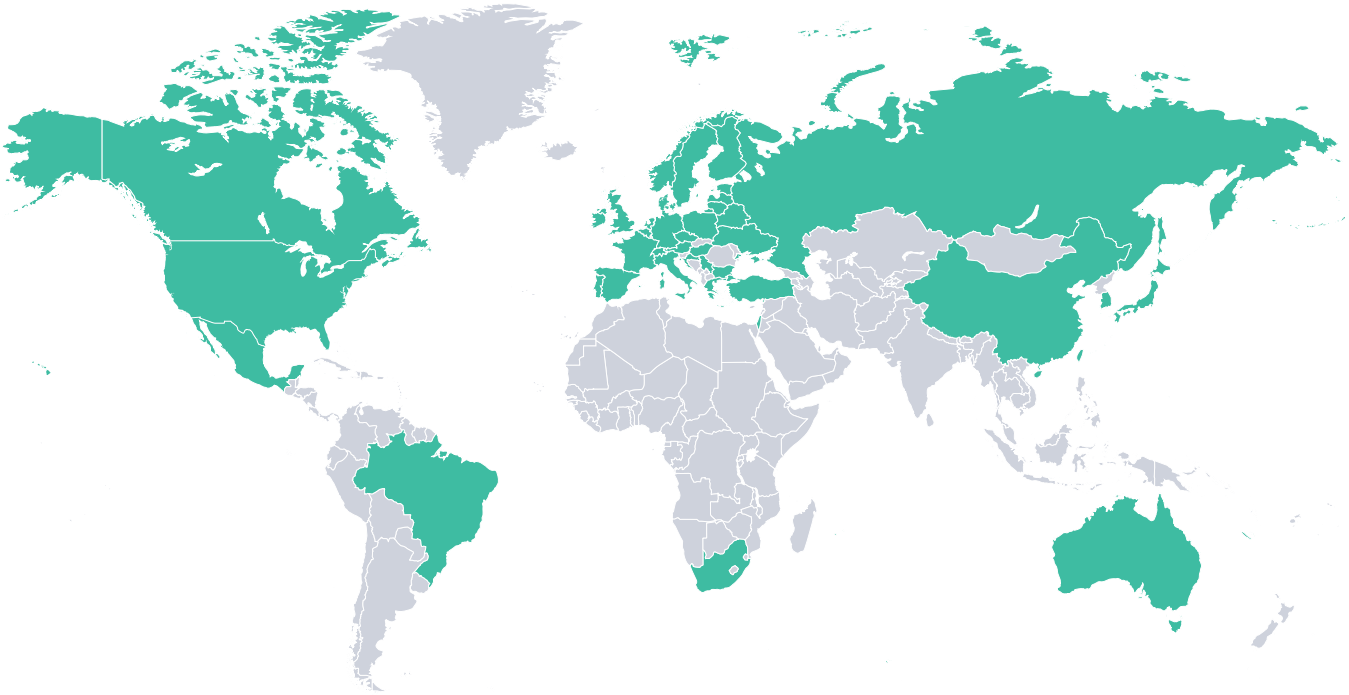
The doctors in this study treated adult patients who were diagnosed with advanced stage small cell lung cancer who previously completed treatment with chemotherapy. Researchers planned this study as a Phase 3, double-blind, randomized study.

- 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 Rova-T versus placebo in patients.
- A placebo is something that looks like the treatment being tested (in this case, an injection that looks like Rova-T) but contains no real medicine. Researchers used a placebo to compare the results for patients who took Rova-T with the results for patients who took placebo.
- This study was also randomized and "double-blinded", which means that patients were randomly (by chance) assigned to treatment groups, and neither the patients nor the study doctors knew who was given Rova-T or who was given placebo.

The main aim of the study was to find out whether Rova-T taken after chemotherapy increases the length of time (during and after treatment) that a patient lives with cancer while it does not get worse. The study also compared how long patients lived (overall survival) if they received Rova-T versus placebo following completion of chemotherapy. The study doctors also looked for any side effects patients might 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.

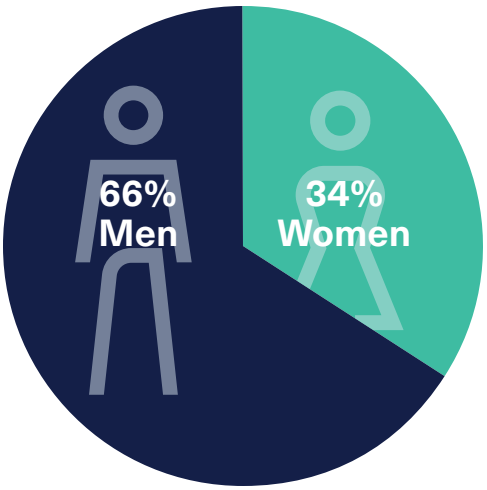
1.2. When and where was the study done?

This study took place from February 2017 to November 2019 in the following countries: Australia, Austria, Belarus, Belgium, Brazil, Bulgaria, Canada, China, Croatia, Czechia , Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Mexico, Netherlands, Norway, Poland, Portugal, Russia, Serbia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, Ukraine, United Kingdom, and United States.



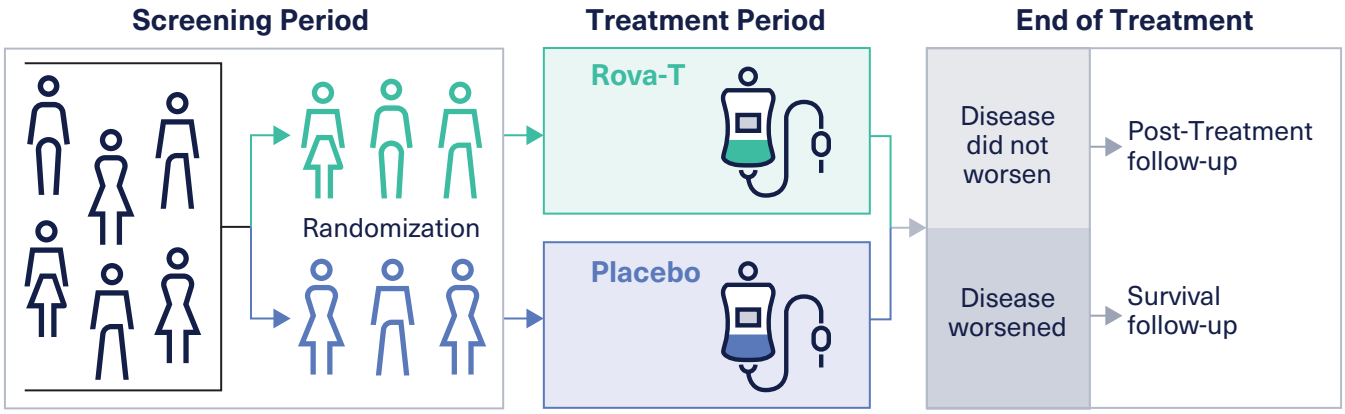
2. What patients were included in this study?

A total of 748 adult patients took part in the study, 741 of which took study drug or placebo. All patients left the study, mostly due to patient death (57%) or because the study sponsor ending the study early (40%). More men (66%) than women (34%) participated in the study. Study doctors selected only adults to participate in this study. Patients ranged from 38 to 94 years of age, with an average age of 64 years. The majority of patients were past smokers (64%) or current smokers (32%), which is typical for this type of lung cancer. Patients must have had advanced stage small cell lung cancer and completed chemotherapy treatment, having shown a beneficial response to treatment before participating in this study.



3. Which medicines were studied?

The medicine in this study was rovalpituzumab tesirine (Rova-T) or placebo. The diagram below shows how the study was organized.



The study was divided into:

- Screening Period – Before the study started, the Screening Period took place to check if patients met the entry criteria so they could join the study. Once patients were screened, they were randomly (by chance) assigned to treatment groups (Rova-T or placebo treatment) without the patients or study doctors knowing who was given which treatment.
- Treatment Period (each cycle = 6 weeks) – In the Treatment Period, Rova-T or placebo was given to patients as an injection into the vein over time (IV infusion) on Day 1 of each cycle. No treatment was given to patients every third cycle. Patients had visits with study doctors on Days 1 and 22 of each treatment cycle and regular phone checks of their overall health and to monitor changes in their cancer.
- Post-Treatment Follow-Up – Patients continued to receive treatment until their cancer worsened or they discontinued the study treatment. Patients who discontinued the study without worsening of their cancer were called by study doctors once every 6 weeks to check the condition of their cancer until the study ended, the patient withdrew from the study, or until patient death.
- Survival Follow-Up – 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 6 weeks (to measure how long each patient lived) until death.

4. What were the side effects

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study, and they may or may not be related to the disease.

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.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to the study treatment (Rova-T or placebo).

- About 42.7% of patients (157 patients) who received Rova-T, and 23.3% of patients (87 patients) who received placebo had serious side effects during the study.
- About 19.3% of patients (71 patients) who received Rova-T, and 3.2% of patients (12 patients) who received placebo had serious side effects considered possibly related to study treatment.
- About 20.1% of patients (74 patients) who received Rova-T stopped treatment because of side effects during the study; 16.8% of patients (61 patients) stopped treatment with Rova-T because of side effects considered possibly related to study treatment.
- About 7.0% of patients (26 patients) who received placebo stopped treatment because of side effects during the study; 1.1% of patients (4 patients) stopped treatment with placebo because of side effects considered possibly related to study treatment.
- A total of 9.5% of patients (35 patients) who received Rova-T died as a result of side effects; six of these side effects were considered to be possibly related to study treatment. A total of 9.9% of patients (37 patients) in the placebo group died during the study as a result of side effects; none of these side effects were considered possibly related to study treatment.

The table below shows information about the related serious side effects patients had during the study (in 4 or more patients overall), as well as related side effects patients had that led to the patient stopping the study treatment, and related side effects leading to death.

Overall Study		
	Placebo (N=373 patients)	Rova-T (N=368 patients)
Number of patients with related serious side effects	12 (3.2% of patients)	71 (19.3% of patients)
Related serious side effects in 4 or more patients overall		
• Thrombocytopenia (deficiency of blood platelets)	0 (0.0% of patients)	8 (2.2% of patients)
• Pericardial effusion (extra fluid in the space around the heart)	2 (0.5% of patients)	3 (0.8% of patients)
• Pneumonia (lower respiratory lung infection that causes inflammation)	0 (0.0% of patients)	4 (1.1% of patients)
• Dyspnea (shortness of breath)	0 (0.0% of patients)	4 (1.1% of patients)
• Pleural Effusion (extra fluid in the space between the lungs and the chest wall)	0 (0.0% of patients)	18 (4.9% of patients)
• Pneumonitis	0 (0.0% of patients)	6 (1.6% of patients)

Overall Study (continued)		
	Placebo (N=373 patients)	Rova-T (N=368 patients)
Number of patients who stopped taking study drug because of related side effects	4 (1.1% of patients)	61 (16.8% of patients)
• Side effect(s)	Decreased platelet count, hyperbilirubinemia (too much bilirubin in the blood), intracranial hemorrhage (ruptured blood vessel in the brain), seizure	Pleural effusion (extra fluid in the space between the lungs and the chest wall), pneumonitis (lung inflammation), thrombocytopenia (deficiency of blood platelets), pericardial effusion (extra fluid in the space around the heart), photosensitivity reaction (allergic reaction to the sun), face edema (swelling of the face), pneumonia (lower respiratory lung infection that causes inflammation), alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, hepatic enzyme increased, blood alkaline phosphatase increased (each abnormal increase in a liver enzyme), erythema (skin redness), pruritus (fever), pancytopenia (low blood cell count), lacrimation increased (excessive tearing), photophobia (light sensitivity), dysphagia (difficulty swallowing), fatigue (tiredness), general physical health deterioration, localized edema (swelling at a certain spot), edema peripheral (swelling of lower legs or hands), hepatitis, hepatotoxicity (chemically-caused liver damage), liver disorder, cellulitis (skin infection), bone pain, fasciitis (inflammation of the fascia), muscular weakness, polyneuropathy (multi-nerve damage), dyspnea (shortness of breath), skin necrosis (skin cell death), Stevens-Johnson syndrome, capillary leak syndrome
Number of related side effects leading to death	0 (0.0% of patients)	6 (1.6% of patients)
• Side effect(s)	–	General physical health deterioration, pneumonia, pneumonitis (lung inflammation; 3 patients), respiratory failure

About 343 patients (93.2% of patients) who received Rova-T, and 304 patients (81.5% of patients) who received placebo had side effects during the study. The total number of patients that had side effects considered possibly related to Rova-T was 290 patients (78.8% of patients) and to placebo was 145 patients (38.9% of patients).

The table below shows information about the common related side effects (in at least 5% or more patients overall) in this study. The most common related side effect was fatigue (tiredness) and edema peripheral (swelling of the lower legs or hands).

Overall Study		
	Placebo (N=373 patients)	Rova-T (N=368 patients)
Number of patients with at least one related side effect	145 (38.9% of patients)	290 (78.8% of patients)
Related side effects in 5% or more patients overall		
• Fatigue (tiredness)	32 (8.6% of patients)	67 (18.2% of patients)
• Edema peripheral (swelling of lower legs or hands)	17 (4.6% of patients)	82 (22.3% of patients)
• Photosensitivity reaction (allergic reaction to the sun)	5 (1.3% of patients)	90 (24.5% of patients)
• Pleural effusion (extra fluid in the space between the lungs and the chest wall)	5 (1.3% of patients)	74 (20.1% of patients)
• Decreased appetite	20 (5.4% of patients)	58 (15.8% of patients)
• Nausea	22 (5.9% of patients)	49 (13.3% of patients)
• Thrombocytopenia (deficiency of blood platelets)	1 (0.3% of patients)	62 (16.8% of patients)
• Pericardial effusion (extra fluid in the space around the heart)	4 (1.1% of patients)	52 (14.1% of patients)
• Aspartate aminotransferase increased (abnormal increase in a liver enzyme)	5 (1.3% of patients)	37 (10.1% of patients)
• Face edema (swelling of the face)	2 (0.5% of patients)	35 (9.5% of patients)
• Dyspnea (shortness of breath)	4 (1.1% of patients)	35 (9.5% of patients)

5. What were the overall results of the study?

The results of this study showed that there was no improvement in overall survival for patients who received rovalpituzumab tesirine (Rova-T) compared to placebo. However, the average length of time before disease progression was longer for patients who received Rova-T compared to patients who received placebo. Overall, there was a higher number of side effects in patients who received Rova-T compared to patients who received placebo. As no survival benefit was found among patients who received Rova-T compared to placebo, this study was ended early.

6. How has the study helped patients and researchers?

The results of this study found no significant benefit of treatment with Rova-T compared to placebo. Findings from this study may be used in other studies with similar patient populations.

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?

AbbVie will not be conducting any future studies with Rova-T.

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, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects With Extensive Stage Small Cell Lung Cancer (MERU)
• Protocol Number	M16-298
• Clinicaltrials.gov	NCT03033511 https://clinicaltrials.gov/ct2/show/NCT03033511?term=M16-298&draw=2&rank=1
• EudraCT	2016-003503-64
• Study Sponsor	AbbVie Inc. Phone: (800) 633-9110 Email: abbvieclinicaltrials@abbvie.com

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!