The Clinical Trial
RESULTS

Roche

Research Sponsor: F. Hoffmann-La Roche Ltd.

Drug Studied: Atezolizumab

Short Study Title: A study to learn about using the drug atezolizumab as a treatment for patients with non-small cell lung cancer

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Thank you!

Thank you for taking part in the clinical study for the study drug atezolizumab. You and all of the other participants helped researchers learn more about using atezolizumab as a treatment for patients with non-small cell lung cancer, also called NSCLC.

F. Hoffmann-La Roche sponsored this study and thinks it is important for you to know the results of the study so far. An independent nonprofit organization called CISCRP and a medical writing organization called Synchrogenix helped prepare this summary of the results for you.

We hope this helps you understand the results and makes you feel proud of your important role in medical research. If you have questions about the results, please speak with your doctor, research nurse, or other team member at your clinic or hospital.

What is happening with the study now?

Your study started in March 2014 and is still going on. A total of 1225 patients from 194 clinics and hospitals in 31 countries participated in this study.

The sponsor reviewed the results for the first 850 patients, which were collected up to July 2016, and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers were looking for a different way to treat NSCLC. In this study, researchers wanted to learn more about using the study drug atezolizumab as a treatment for patients with NSCLC. Researchers also wanted to find out if patients had any medical problems during the study.

Your body's infection-fighting system, called the immune system, naturally fights against cancer cells. Atezolizumab makes cancer cells weaker against your immune system. So, atezolizumab may help your own body stop tumors from growing, or even reverse the process.

Certain chemotherapy medicines that contain a metal called platinum are usually the first choice to treat NSCLC. But, some patients still get worse after this treatment. In this study, researchers compared atezolizumab to a drug called docetaxel. Docetaxel is another treatment for NSCLC that does not contain platinum. This drug stops cancer cells from dividing into several more cells, which keeps tumors from growing. So, doctors may give patients docetaxel if medicines containing platinum do not work.

The main questions researchers wanted to answer in this study were:

- Did patients who got atezolizumab live longer than patients who got docetaxel?
- How long did atezolizumab prevent NSCLC from getting worse compared to docetaxel?
- Did atezolizumab shrink tumors more than docetaxel?
- How long did patients live without their cancer getting worse if their tumors shrank?
- What adverse events did patients have? An adverse event is a medical problem that may or may not be caused by the study drug.

What kind of study was this?

Your study was "open-label". This means that the patients, doctors, and study staff knew what drugs patients were getting.

The researchers used a computer program to randomly choose if you got atezolizumab or docetaxel. This is done in clinical studies to help make sure the treatments are assigned fairly and the results are as accurate as possible.

Your study included women and men with NSCLC who were between the ages of 33 and 85 years. All patients in this study had NSCLC that got worse during or after previous treatment with a type of chemotherapy that contained platinum.

What happened during the study?

Before the study began, the study doctors checked your health to make sure you could join the study. This included a physical exam, checking your heart health, and taking blood and urine samples from you.

The study doctors also:

- Checked your cancer by taking images of the tumors using either magnetic resonance imaging scans, also called MRIs, or computed tomography scans, also called CTs.
- Asked about your lung cancer symptoms, how you were feeling, and what medicines you were taking.

During the study, you got the study treatments intravenously. This means the treatment was injected into a vein using a needle. The study doctors took images of tumors to see if and how they were responding to the treatments. The chart below shows how treatments were given in your study.

425 patients got atezolizumab	425 patients got docetaxel
You got treatment for as long as you could tolerate treatment and your study doctor felt that treatment was helping you.	You got treatment for as long as you could tolerate treatment and your tumor did not grow.
Each injection was 1200 "mg", which is also called "milligrams"	Each injection was 75 "mg/m^2", also called "milligrams per square meter of body area"

After treatment ended, you visited the study clinic within 30 days after your last treatment dose for a follow-up visit. After that, the study doctors checked on you every 2 to 3 months. The study doctors asked you how you were feeling, what medicines you were taking, and how your lung cancer symptoms were. The chart below shows what happened during the study.

During study treatment	After treatment ended
Treatment Injections of atezolizumab or docetaxel every 3 weeks	**Visits and check in on well-being** Clinic visit within 30 days of last treatment Then check-ups every 2-3 months The study doctors asked about cancer symptoms They also took more images of tumors
Images of tumors taken every 6 weeks for the first 36 weeks and then every 9 weeks afterwards	

What were the study results?

Below is a summary of the results of some of the questions that researchers asked during this study for all patients worldwide up to July 2016. It is important to know that researchers and regulatory health authorities look at the results of many studies to decide which medicines work best and are safest for patients.

A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

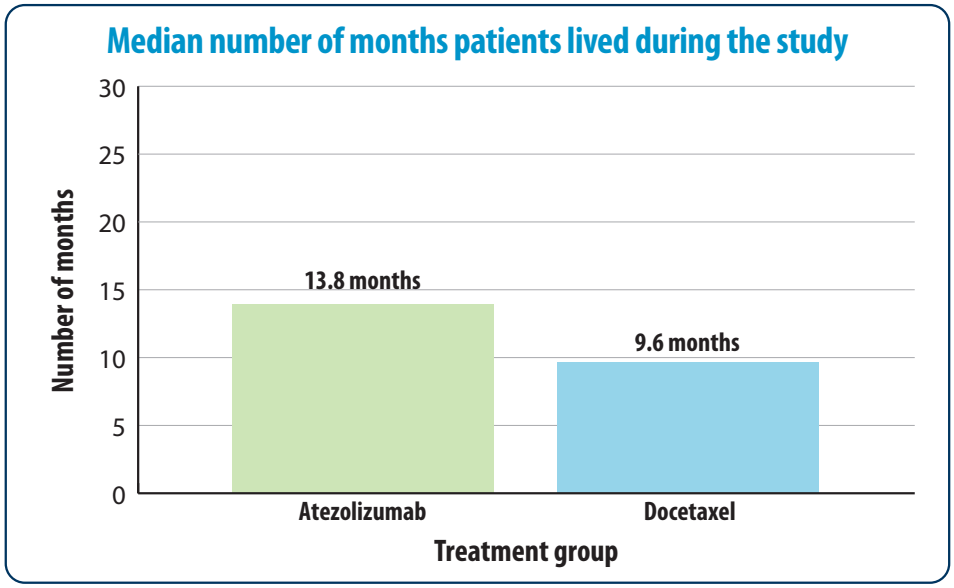
Did patients who got atezolizumab live longer than patients who got docetaxel?

Yes. Researchers found that patients who got atezolizumab lived longer during the study than patients who got docetaxel.

At the time data were analyzed, the researchers found:

- Patients who got atezolizumab lived for about 13.8 months
- Patients who got docetaxel lived for about 9.6 months

These are the "median" lengths of time patients in each group lived. Median means that half of the patients lived less than this length of time, and half lived longer. The graph below shows the median number of months that patients lived during the study.



It is important to know that the results above were for the main question researchers asked. This study was designed to get the most accurate answers to the main question.

The results below are for other questions researchers asked in order to learn more about the drug and disease. But, more studies need to be done to know if the answers to these questions are accurate.

How long did atezolizumab prevent NSCLC from getting worse compared to docetaxel?

At the time data were analyzed, researchers found that the number of patients who lived without their cancer getting worse was about the same in the atezolizumab group as it was in the docetaxel group. In this study, "getting worse" meant patients had their tumors grow in size or new tumors appeared.

Atezolizumab - Patients in this group lived for about 2.8 months without their cancer getting worse.

Docetaxel - Patients in this group lived for about 4.1 months without their cancer getting worse.

Did atezolizumab shrink tumors more than docetaxel?

No. At the time data were analyzed, researchers found that the number of patients who had their tumors shrink was about the same in the atezolizumab group as it was in the docetaxel group:

- 13.6% in the atezolizumab group, or 58 of 425 patients
- 13.4% in the docetaxel group, or 57 of 425 patients

How long did patients live without their cancer getting worse if their tumors shrank?

Researchers measured the median number of months that patients whose tumors got smaller had their tumors stay smaller before their cancer got worse. Researchers found that this period of time was longer for patients who got atezolizumab than for patients who got docetaxel:

- 16.3 months in the atezolizumab group
- 6.2 months in the docetaxel group

What medical problems did patients have during the study?

When new drugs are being studied, study doctors keep track of all of the medical problems that patients develop during the study. These medical problems are called "adverse events", and may or may not be caused by the study drug. An adverse event is considered serious when it is life-threatening, makes you go to the hospital, or causes lasting problems.

How many patients had adverse events during the study?

Out of the 1225 patients who enrolled, adverse events were studied for the 1187 patients who got at least 1 dose of either atezolizumab or docetaxel. Most patients had at least 1 adverse event. A similar number of patients in both treatment groups had adverse events and serious adverse events. Some patients stopped taking the study drugs because of a serious adverse event. The table below shows how many patients had adverse events during this study.

Adverse events in this study

	Atezolizumab (Out of 609 patients)	Docetaxel (Out of 578 patients)	Total (Out of 1187 patients)
How many patients had at least 1 adverse event?	94.1% (573)	96.0% (555)	95.0% (1128)
How many patients had at least 1 serious adverse event?	31.9% (194)	31.3% (181)	31.6% (375)
How many patients stopped taking any study drug because of an adverse event?	7.6% (46)	18.7% (108)	13.0% (154)

What were the most common serious adverse events?

In this study, pneumonia was the most common serious adverse event. The table below shows the most common serious adverse events that happened in at least 2% of patients in either treatment group. There were other serious adverse events, but fewer patients had them.

Serious adverse events in this study

	Atezolizumab (Out of 609 patients)	Docetaxel (Out of 578 patients)	Total (Out of 1187 patients)
Pneumonia	3.3% (20)	5.4% (31)	4.3% (51)
Difficulty breathing	2.0% (12)	1.4% (8)	1.7% (20)
Fluid buildup between the lungs and chest	2.0% (12)	1.0% (6)	1.5% (18)
Fever with low white blood cell count	0.0% (0)	6.4% (37)	3.1% (37)

A similar number of patients in both treatment groups died:

- 62.9% taking atezolizumab died. This happened in 383 of the 609 patients.
- 69.6% taking docetaxel died. This happened in 402 of the 578 patients.

Study doctors thought that most of these deaths were due to patients' cancer getting worse.

Some patients died because of adverse events:

- 16.1% taking atezolizumab died from adverse events within 30 days of their last dose. This happened in 10 of the 609 patients.
- 33.3% taking docetaxel died from adverse events within 30 days of their last dose. This happened in 14 of the 578 patients.

Study doctors thought that 1 death from an adverse event in the docetaxel group might be related to study treatment. This patient died from a respiratory infection.

What were the most common adverse events?

In this study, tiredness was the most common adverse event. The table below shows the most common adverse events that happened in at least 20% of patients in either treatment group. There were other adverse events, but fewer patients had them.

Most common adverse events in this study

	Atezolizumab (Out of 609 patients)	Docetaxel (Out of 578 patients)	Total (Out of 1187 patients)
Tiredness	26.8% (163)	35.5% (205)	31.0% (368)
Decreased appetite	23.5% (143)	23.5% (136)	23.5% (279)
Cough	23.2% (141)	18.2% (105)	20.7% (246)
Nausea	17.7% (108)	22.7% (131)	20.1% (239)
Diarrhea	15.4% (94)	24.4% (141)	19.8% (235)
Anemia (having a low red blood cell count)	11.5% (70)	23.5% (136)	17.4% (206)
Hair loss	0.5% (3)	34.9% (202)	17.3% (205)

What is important to know about these results?

Patients in this study had NSCLC that had worsened during or after previous treatment with chemotherapy. Researchers compared atezolizumab to docetaxel as treatment for these patients. At the time data were analyzed, researchers found that patients who got atezolizumab lived longer during the study than patients who got docetaxel. This study is still going on, and study doctors are still collecting information from patients who are still in the study. Further clinical studies with atezolizumab are planned.

Doctors and researchers look at results of many studies to decide which drugs work best and are safest for patients. The results presented here are for a single study. Other studies may provide new information or different results.

Where can I learn more about this study?

You can find more information about your study on the websites listed below.

- www.clinicaltrials.gov. Once you are on the website, type **NCT02008227** into the search box called **"Other Terms"**. Then, click **"Search all studies"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**. Then, type **2013-003331-30** in the search box and click **"Search"**.

If you have questions about the results, please speak with the doctor, research nurse, or other team member at your clinic or hospital.

Please also refer to the informed consent form you signed before joining this study for more details about your study.

The full title of your study is: A Phase III, open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab (anti-PD-L1 antibody) compared with docetaxel in patients with non-small cell lung cancer after failure with platinum-containing chemotherapy (OAK)

The protocol number of your study is: GO28915

F. Hoffmann-La Roche sponsored this study. Its address and contact information are:
Grenzacherstrasse 124 CH-4070
Basel, Switzerland
Telephone number: +41-61-688-1111
Email: global.rochegenentechtrials@roche.com

Thank you

Clinical trial patients belong to a large community of people who take part in clinical research around the world. They helped researchers answer important health questions and find medical treatments for patients. It takes patients in many studies all around the world to advance medical science.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.

CISCRP One Liberty Square, Suite 510, Boston, MA 02109 • 1-877-MED-HERO • www.ciscrp.org