Clinical Trial RESULTS

Roche

Research Sponsor: F. Hoffmann-La Roche Ltd
Drug Studied: Atezolizumab (MPDL3280A)
National Clinical Trial #: NCT01903993
EudraCT Number: 2013-001142-34
Protocol #: GO28753
Results from Study Dates: August 2013 to May 2015
Full Title of Your Study: A Phase 2, 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 Platinum Failure

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the global clinical study for the study drug atezolizumab. Researchers studied this treatment for use in patients with non-small cell lung cancer, or NSCLC. You and the other patients helped researchers compare the effects of atezolizumab to another chemotherapy drug called docetaxel.

F. Hoffmann-La Roche, the sponsor of this study, thanks you for your help and thinks it is important for you to know the main results of your study. An independent non-profit organization called CISCRP and a medical writing organization called Synchrogenix prepared this summary of the trial results for you. We hope it 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 study center.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

WHAT'S HAPPENED SINCE I JOINED THE STUDY?

Your study began in August 2013. This summary tells you the results up to May 2015. Your study is still going on, and doctors are still collecting information. Some patients are still taking the study treatment.

Your study included 287 patients from 13 countries around the world. A total of 277 patients at 61 study centers received at least 1 dose of a study drug. In December 2015, the sponsor reviewed the data collected up to May 2015 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 non-small cell lung cancer, or NSCLC. Certain chemotherapy medicines that contain platinum are usually the first choice to treat NSCLC. But many patients still get worse after this treatment.

A medicine called docetaxel is another treatment for NSCLC. It stops cancer cells from dividing. This helps keep tumors from growing. So doctors may give docetaxel if medicines with platinum do not work.

Atezolizumab is an experimental drug for NSCLC and other cancers. It works differently than docetaxel. Your body's infection-fighting system, called the immune system, naturally fights against cancer cells. Atezolizumab makes cancer cells less able to resist your immune system. So atezolizumab may help your own body stop tumor growth or reverse it. Researchers wanted to compare the effects of atezolizumab and docetaxel on you and your NSCLC to find out which is better.

In your study, researchers wanted to learn:

- Did patients who took atezolizumab live longer than patients who took docetaxel?
- Did atezolizumab shrink tumors more than docetaxel?
- How long did atezolizumab prevent NSCLC from getting worse compared to docetaxel?
- Did patients who took atezolizumab maintain their quality of life longer than patients who took docetaxel?
- How did atezolizumab act in the body?
- What adverse events did patients have? An adverse event is a medical problem that may or may not be caused by the study drug.

This study was for men and women who were at least 18 years old. All of them had NSCLC that got worse with a type of chemotherapy that contained platinum.

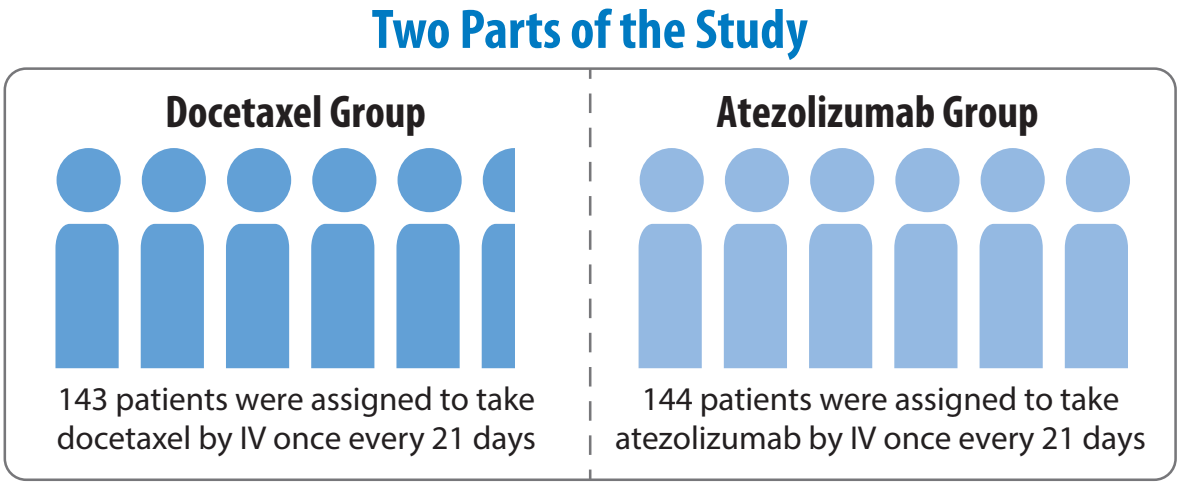
WHAT KIND OF STUDY WAS THIS?

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

Patients in your study were randomly assigned to receive 1 of the treatments below:

- Atezolizumab
- Docetaxel

The picture below shows how many patients were assigned to each treatment.



WHAT HAPPENED DURING THE STUDY?

Patients received the study treatments by IV (into a vein) once every 21 days.

If you were in the **docetaxel group**, you could keep receiving treatment until your tumor grew.

If you were in the **atezolizumab group**, you could keep receiving treatment until the study doctor decided that you were not benefitting from the treatment. Because atezolizumab works differently than some other cancer treatments, patients in the atezolizumab group could keep taking it even if the tumor grew. They could take it as long as study doctors thought atezolizumab was helping.

While you were receiving study treatment, your doctors and nurses regularly checked your health and ability to do daily activities. You answered questions about how you were feeling, had physical examinations, and had blood and urine tests. You also had heart tests and scans to check your tumors and learn if your cancer got worse. The study doctors and nurses also kept track of any adverse events that you and other patients had.

After you stopped taking study treatment, study staff contacted you every 3 months to check on your health and ask about any new cancer medicines you were taking.

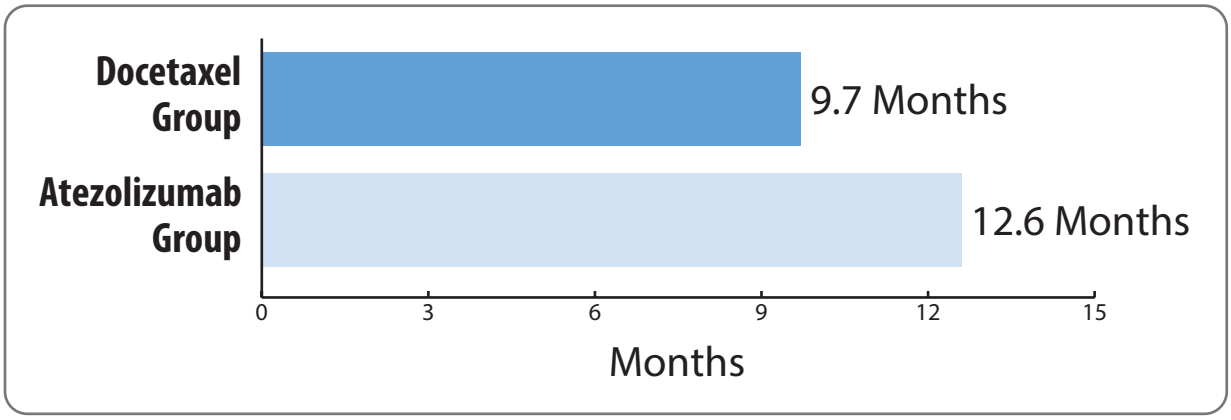
WHAT WERE THE STUDY RESULTS?

This section is a summary of the main medical questions that were asked in this study and the results so far. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Clinical studies with atezolizumab are ongoing in patients with NSCLC, and further studies are planned in patients with NSCLC and other cancers.

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

Yes. Researchers found that patients in the atezolizumab group lived almost 3 months longer than patients in the docetaxel group. Patients in the docetaxel group lived about 9.7 months and patients in the atezolizumab group lived about 12.6 months. These are the "median" lengths of time patients in each group lived. Median means half of the patients lived less than this length of time, and half lived longer. The graph below shows how long patients in each group lived during the study.

How Long Patients in Each Group Lived During the Study



Did atezolizumab shrink tumors more than docetaxel?

Researchers looked at how many patients had tumors shrink (get smaller) during the study. They also looked at how long the tumors stayed smaller.

- The percentage of patients whose tumors got smaller was the same in each group (15%).
- The patients who had tumors get smaller had their tumors stay smaller for 14.3 months in the atezolizumab group and 7.2 months in the docetaxel group. This was almost twice as long in patients taking atezolizumab compared to the docetaxel group.

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

Researchers thought that patients' NSCLC was getting worse if the tumor grew or spread to other parts of the body during the study. It took about 3 months until NSCLC got worse in both groups. Half the patients got worse sooner and half got worse later.

- 3 months until NSCLC got worse in the docetaxel group
- 2.7 months until NSCLC got worse in the atezolizumab group

Did patients who took atezolizumab maintain their quality of life longer than patients who took docetaxel?

No. Patients in both groups reported feeling about the same about their quality of life throughout the study.

How did atezolizumab act in the body?

Patients in the atezolizumab group had blood samples to check how much of this drug was in their blood. Researchers found that:

- The amount of atezolizumab in the blood was highest after the first dose.
- The minimum amount of atezolizumab in the blood reached a steady amount after 4 to 8 doses.

WHAT ADVERSE EVENTS DID PATIENTS HAVE?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, study doctors keep track of all of the medical problems that patients have. These medical problems are called "adverse events", and may or may not be caused by the study drug. This section tells you about the adverse events that happened in your study.

How many patients had adverse events?

Most patients had at least 1 adverse event. Some patients in each group stopped taking the study drug because of an adverse event. Out of the 287 patients assigned to a treatment in the study, 277 patients received at least 1 dose of treatment: 135 in the docetaxel group and 142 in the atezolizumab group.

The table below shows how many patients in each group had adverse events. It also shows how many patients stopped taking study drugs because of them.

	Docetaxel Group (Out of 135 patients)	Atezolizumab Group (Out of 142 patients)
How many patients had at least 1 adverse event?	130 patients (96.3%)	136 patients (95.8%)
How many patients had at least 1 serious adverse event?	46 patients (34.1%)	50 patients (35.2%)
How many patients stopped taking the study drug because of an adverse event?	30 patients (22.2%)	11 patients (7.7%)

What serious adverse events did participants have?

An adverse event is considered serious when it is life-threatening, makes you go to the hospital, or causes lasting problems.

In your study, 96 patients (34.7%) had at least 1 serious adverse event. The most common serious adverse events that happened in at least 2% of patients in either group are shown in the table below. There were other serious adverse events, but fewer patients had them.

Serious Adverse Events in This Study	Docetaxel Group (Out of 135 patients)	Atezolizumab Group (Out of 142 patients)
Pneumonia	3 patients (2.2%)	8 patients (5.6%)
Blood clot in lung	6 patients (4.4%)	2 patients (1.4%)
Shortness of breath	1 patient (0.7%)	7 patients (4.9%)
Fever with low white blood cell count	7 patients (5.2%)	0 patients (0%)
Coughing up blood	3 patients (2.2%)	1 patient (0.7%)
Fever	1 patient (0.7%)	3 patients (2.1%)
Fluid build-up around the lungs	0 patients (0%)	4 patients (2.8%)
Blood infection	3 patients (2.2%)	0 patients (0%)

Out of the 287 patients assigned to a treatment in the study, there were 173 patients who died during the study. This included 95 patients in the docetaxel group and 78 patients in the atezolizumab group. Most of the deaths were caused by the cancer getting worse. Study doctors thought that 3 deaths from adverse events in the docetaxel group and 1 death from an adverse event in the atezolizumab group might be related to study treatment.

- 1 patient in the docetaxel group died from a condition called "acute respiratory distress syndrome," or ARDS. This happens when there is inflammation in the lungs. The inflammation keeps oxygen from getting into the lungs.
- 1 patient in the docetaxel group died from a blood infection
- 1 patient in the docetaxel group died from an unknown cause
- 1 patient in the atezolizumab group died from heart failure

What were the most common adverse events?

The table below shows the most common medical problems that happened in at least 25% of patients in either group. There were other medical problems, but fewer patients had them.

Most Common Adverse Events in this Study	Docetaxel Group (Out of 135 patients)	Atezolizumab Group (Out of 142 patients)
Tiredness	54 patients (40.0%)	55 patients (38.7%)
Decreased appetite	28 patients (20.7%)	49 patients (34.5%)
Nausea	45 patients (33.3%)	31 patients (21.8%)
Cough	33 patients (24.4%)	38 patients (26.8%)
Shortness of breath	27 patients (20.0%)	38 patients (26.8%)
Diarrhea	38 patients (28.1%)	24 patients (16.9%)
Hair loss	52 patients (38.5%)	3 patients (2.1%)

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

You can find more information about your study online at https://clinicaltrials.gov/ct2/show/results/NCT01903993 or https://www.clinicaltrialsregister.eu/ctr-search/search?query=2013-001142-34. If you have questions about the results, please speak with the doctor or staff at your study center.

F. Hoffmann-La Roche, the sponsor of this study, has its headquarters at Grenzacherstrasse 124 CH-4070, Basel, Switzerland.

The phone number for general information is +41-61-688-1111.

Thank you

It is said that the greatest gift is one that is given anonymously, given when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge. Thank you for the gift of your participation in clinical research.

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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 participants for clinical trials, nor is it involved in conducting clinical trials.

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