

## A study of atezolizumab (immunotherapy) compared with supportive care given after chemotherapy in people who had successful surgery for a type of lung cancer called ‘non-small cell lung cancer’

See the end of the summary for the full title of the study.

### About this summary

This is a summary of the results of a clinical trial (called a ‘study’ in this document) – written for:

- Members of the public
- People who took part in the study and other patients.

This summary is based on information known at the time of writing.

The study started in October 2015 and is expected to end in December 2027. This summary includes the results that were analysed in January 2021. At the time of writing this summary, the study is still ongoing, and study doctors are still collecting information.

The results from this study may be different from other studies with the same medicine. One study can’t tell us everything about **how safe a medicine is and how well it works**. It takes lots of people in many studies to find out everything we need to know.

**This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.**

### Contents of the summary

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### Glossary

- NSCLC = non-small cell lung cancer
- BSC = best supportive care

### Thank you to the people who took part in this study

The people who took part in this study have helped researchers answer important questions about a type of lung cancer called ‘non-small cell lung cancer’ (NSCLC) and the medicine being studied – ‘atezolizumab’. Atezolizumab was taken after chemotherapy given to people after they had surgery to completely remove their NSCLC.

## Key information about this study

### Why was this study done?

- This study is being done to see how well atezolizumab works to stop or delay NSCLC from coming back after surgery and how safe it is when given after chemotherapy to people with NSCLC who have had their lung cancer completely removed with surgery.
- After they finished chemotherapy following surgery, people were given either the medicine being studied (called '**atezolizumab**') or they were given **no medicine**. **The people who received no medicine** were still checked by doctors to see if the cancer came back, which is the usual type of care and called 'best supportive care' or 'BSC'.
- Overall, 1280 people in 22 countries/regions joined this study.
- Researchers looked at how well atezolizumab worked in the 1005 people who received **atezolizumab or BSC**, based on:
  1. Whether or not the NSCLC had a protein marker called 'programmed death-ligand 1' or '**PD-L1**' on it
  2. How advanced the NSCLC was (ranging from '**stage IB**' – meaning the cancer was only in the lungs, to '**stage II or IIIA**' – meaning the cancer may have spread from the lungs to lymph nodes in and around the lungs). Please note that the Stage categories can change based on new data and the staging categories for NSCLC have changed recently.

### What were the results?

- So far, the main findings were that:
  - Among the people in the **BSC group** with **stage II-III A NSCLC who had PD-L1 protein marker on their tumours**, it took an average of **35 months** for the cancer to come back after surgery, new NSCLC to be found, or death to occur.
    - This average time could not be calculated in the atezolizumab group because at the time these results were analysed, not enough people (50% or more) had the cancer come back, got new NSCLC, or had died.
  - Among the people in the **atezolizumab group** who had **stage II-III A NSCLC regardless of any PD-L1 protein marker on their tumours**, it took an average of **42 months** for the cancer to come back, new NSCLC to be found, or death to occur, compared with an average of **35 months** in the **BSC group**.
  - Among the people in the **BSC group** who had **stage IB-III A NSCLC regardless of any PD-L1 protein marker on their tumours**, it took an average of **37 months** for the cancer to come back, new NSCLC to be found, or death to occur.
    - This average time could not be calculated in the atezolizumab group because at the time these results were analysed, not enough people (50% or more) had the cancer come back, got new NSCLC, or had died.

### How many people had serious side effects related to their treatment?

- About 7% of people taking atezolizumab (37 out of 495 people), which is the same as 7 out of 100 people) had serious side effects related to atezolizumab.

## 1. General information about this study

### Why was this study done?

When someone is diagnosed with non-small cell lung cancer (NSCLC), doctors will check if it has spread to other parts of the lungs or body, and if so, how far – this is called ‘staging’. The stages describe where the cancer has spread in the body. Stages range from IA to IV. The lower the stage, the smaller the tumour and the less it has spread. For example, a stage IB tumour has not spread to nearby lymph nodes or other parts of the body. Stage IIIA NSCLC may have spread to lymph nodes on the same side as the original tumour.

If NSCLC is found before it has had time to grow and spread too far, it may be possible to completely remove it with surgery – this is known as ‘completely resected NSCLC’. To improve people’s chances of living longer after surgery to remove NSCLC, they are given chemotherapy. Chemotherapy is medicine that kills cancer cells. Chemotherapy given after surgery is called ‘adjuvant chemotherapy’.

**Chemotherapy** that kills cancer cells using a platinum drug is called ‘platinum-based chemotherapy’. This type of treatment involves 2 different types of chemotherapy drugs, taken together. However, chemotherapy may work for only a short time and may kill healthy cells. So, only a few doses can be given. Often, the cancer comes back, or a new cancer can start to grow. New treatments are needed to stop the cancer from coming back or to treat the cancer – shrink the tumour – more effectively, and to help people live longer and with better quality of life.

**Immunotherapy** is a type of medicine that helps a person’s own immune system attack cancer cells. Some immunotherapy medicines do this by finding and targeting a protein called ‘PD-L1’ that is found on some cancer (and normal) cells. Normally, PD-L1 links to another protein called PD-1 on immune cells called T-cells and sends a signal to the person’s immune system to leave the cancer cells alone. Immunotherapy medicines like atezolizumab block PD-L1 and allow the immune system to attack the cancer cells. PD-L1 is found in different amounts on cancer cells – each person’s NSCLC has a different amount of PD-L1. Immunotherapy also works in other ways, so it can still work well, even in people who have cancer with small amounts or no PD-L1.

In this study, researchers wanted to see if:

- 1) Taking an immunotherapy (atezolizumab) after surgery and chemotherapy would stop or delay the NSCLC from coming back and stop new NSCLC for longer than if they received only general follow-up care (also called ‘BSC’).
- 2) Atezolizumab worked in people who had PD-L1 on their NSCLC tumour cells, and how well it worked depending on their NSCLC stage at diagnosis.

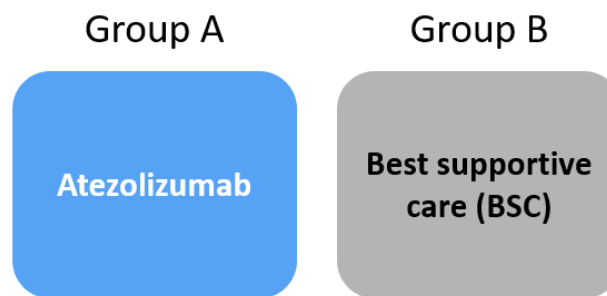
The different amounts of PD-L1 in the tumours were measured by counting tumour cells under a microscope to see the percentage that had PD-L1 protein.

## What were the treatments being studied?

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This study compared the medicine being tested (atezolizumab) to BSC in 2 groups of people who had their lung cancer completely removed by surgery and then had treatment with 1 to 4 cycles of chemotherapy.

- **Group A: Atezolizumab** (study medicine)
- **Group B: BSC**



**Atezolizumab** is the medicine being studied here.

- The body's immune system fights diseases like cancer. However, cancer cells can block (stop) the immune system from attacking the cancer. Atezolizumab releases this blockage – meaning that the immune system is able to fight the cancer cells.
- When people take atezolizumab, their tumour (cancer) may get smaller or stop growing. In people who had their cancer surgically removed, atezolizumab may stop or delay the cancer from coming back. This medicine is a type of immunotherapy.

**BSC** included X-rays and CT scans of people's lungs and body to check for the NSCLC coming back or new NSCLC.

## What did researchers want to find out?

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- Researchers did this study to compare **atezolizumab (Group A)** to **BSC (Group B)** – to see how well atezolizumab worked (see section 4 “What were the results of the study?”).
- They also wanted to find out how safe atezolizumab was – by checking how many people had side effects in each treatment group and seeing how serious they were (see section 5 “What were the side effects?”).

**The main questions that researchers wanted to answer were:**

1. In people with **stage II-III A NSCLC who had PD-L1 on their tumour cells**, how much time was there between the start of treatment and the cancer coming back or new NSCLC being found?
2. In people with **stage II-III A NSCLC regardless of the presence of PD-L1 on their tumour cells**, how much time was there between the start of treatment and the cancer coming back or new NSCLC being found?

3. In people with **stage IB-III A NSCLC regardless of any PD-L1 on their tumours**, how much time was there between the start of treatment and the cancer coming back or new NSCLC being found?

### What kind of study was this?

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This was a '**Phase 3**' study. This means that before this study started, atezolizumab had been tested in a smaller number of people with NSCLC. Phase 3 studies are done in a large number of people to see if a medicine works better than the standard existing treatment and is safe enough for it to be 'approved' by the health authorities as a treatment that doctors can prescribe.

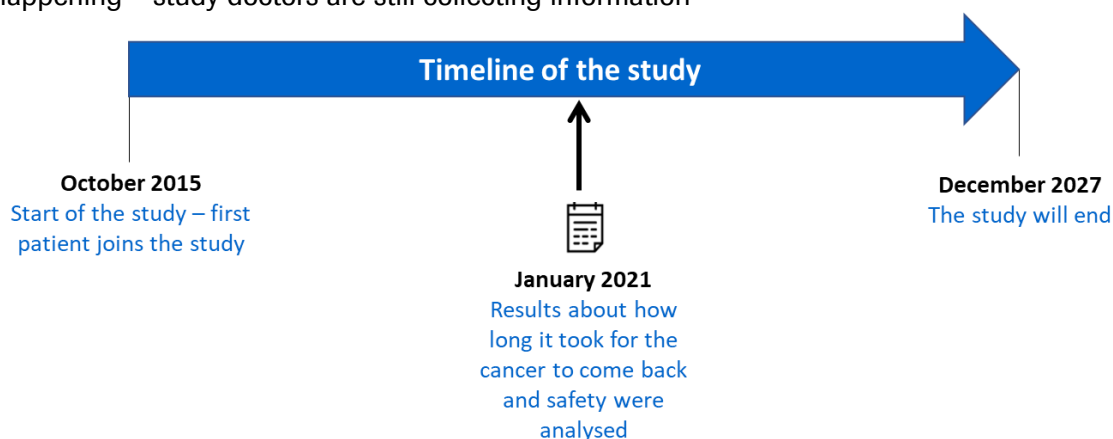
The study was '**randomised**'. This means that it was decided by chance which of the treatments people in the study would be given. Randomly choosing which treatment people get makes it more likely that the types of people in both groups will be a similar mix (for example, similar numbers of men and women, similar stages of disease). Other than the different treatments being given in each group, all other care was the same.

This was an '**open label**' study. This means that both the people taking part in the study and the study doctors knew the study treatments people were taking.

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

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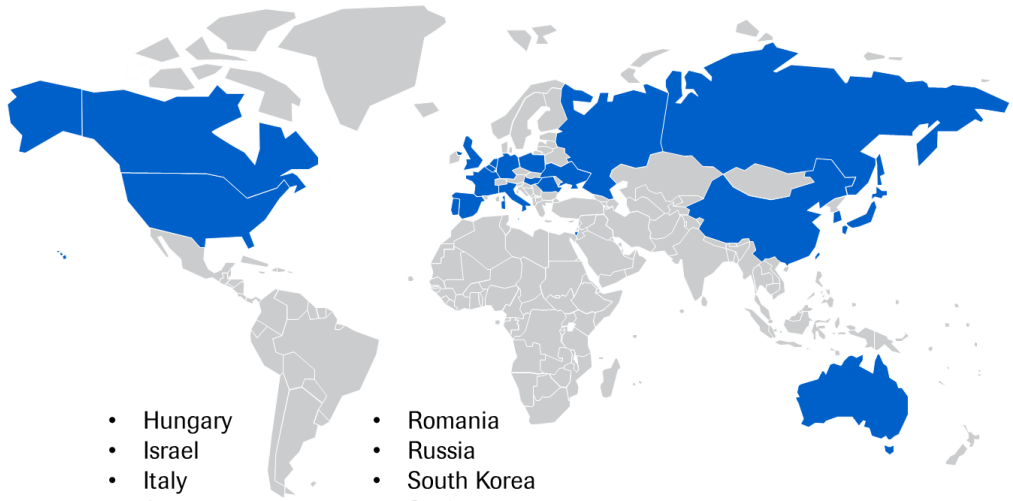
The study started in October 2015 and is expected to end in December 2027. This summary includes the results up until January 2021. At the time of writing this summary, the study is still happening – study doctors are still collecting information



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (January 2021 – about 5 years and 3 months after the study started).

The study took place at 228 hospitals and clinics in 22 countries/regions.

This map shows the countries/regions where this study took place.

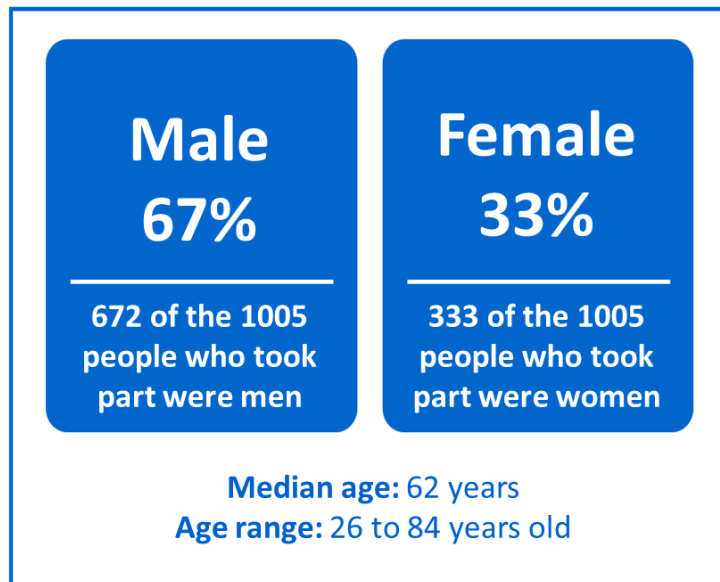


- Australia
- Belgium
- Canada
- China
- France
- Germany
- Hong Kong
- Hungary
- Israel
- Italy
- Japan
- The Netherlands
- Poland
- Portugal
- Romania
- Russia
- South Korea
- Spain
- Taiwan
- Ukraine
- United Kingdom
- United States

## 2. Who took part in this study?

In this study, 1005 people with NSCLC that was completely removed by surgery who had received chemotherapy after surgery were randomised to receive atezolizumab or BSC.

This picture shows more information about the people who took part.



People **could** take part in the study if:

- They had stage IB-IIIa NSCLC, and it was completely removed with surgery.
- Their lymph nodes between the lungs had been checked for cancer.
- They were healthy enough to receive chemotherapy.
- They had allowed their doctor to take a sample of their cancer.

People **could not** take part in the study if:

- They had cancer that could not be removed completely by surgery or that had spread.
- They had an illness that causes their immune system to attack their own body (called an 'autoimmune disease').
- They had previously had other types of lung disease or lung infection.
- They had taken any medicines before for their lung cancer, including other drugs that work like atezolizumab.

People **could** be sorted into Group A or Group B to **get atezolizumab or BSC** if:

- The NSCLC had been completely removed by the surgery.
- They had completed 1 to 4 cycles of chemotherapy after their surgery.
- The NSCLC had not come back.
- Their kidneys and liver worked well.

### 3. What happened during the study?

After the people had recovered from surgery and completed 1 to 4 cycles of chemotherapy, they were chosen at random by a computer to get 1 of 2 treatments.

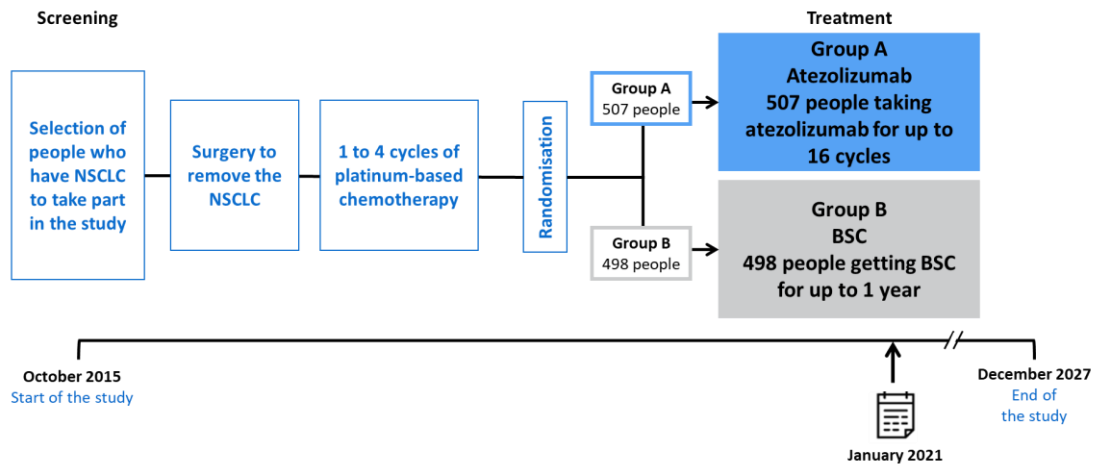
The treatment groups were:

- **Group A:** atezolizumab (new medicine)
- **Group B:** BSC (the usual type of care)

This table shows the number of people in each study group and how often the drug is taken.

	<b>Group A Atezolizumab</b>	<b>Group B BSC</b>
<b>Number of people in group (chosen by computer)</b>	507	498
<b>Number of people with stage II-III A NSCLC and any PD-L1 on their tumours</b>	248	228
<b>Number of people with stage II-III A NSCLC (regardless of any PD-L1 on their tumours)</b>	442	440
<b>Number of people with stage IB-III A NSCLC (regardless of any PD-L1 on their tumours)</b>	507	498
<b>Number of people who received the treatment</b>	495	495
<b>How the drug was taken</b>	Injected into a vein	No drug was taken
<b>When the drug was taken in each 3-week treatment cycle</b>	Day 1	No drug was taken
<b>Planned length of treatment</b>	16 cycles (1 year)	1 year

This picture shows more information about what happened in the study – and what the next steps are.



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (January 2021 – about 5 years and 3 months after the study started).

- The people taking part are asked to go back to their study centre for more visits to check their overall health until the study ends.

## 4. What were the results of the study?

**Question 1:** In people with **stage II-III A NSCLC who had PD-L1 on their tumour cells**, how much time was there between the start of atezolizumab treatment and the cancer coming back, new NSCLC being found, or death occurring?

Researchers looked at how much time there was before the NSCLC came back after surgery, a new NSCLC was found, or death occurred in people with **stage II-III A NSCLC who had PD-L1** on their tumour cells in the **atezolizumab group** and **BSC group**. This information was collected from October 2015 until January 2021.

Results were collected and analysed for 248 people in the **atezolizumab group** and 228 people in the **BSC group**.

- In the **atezolizumab group**, the average time **could not be calculated** because at the time these results were analysed, not enough people (50% or more) had their cancer come back, got new NSCLC, or had died.
- In the **BSC group**, it took an average of **35 months**. In some people it took longer and in others it occurred sooner than 35 months.



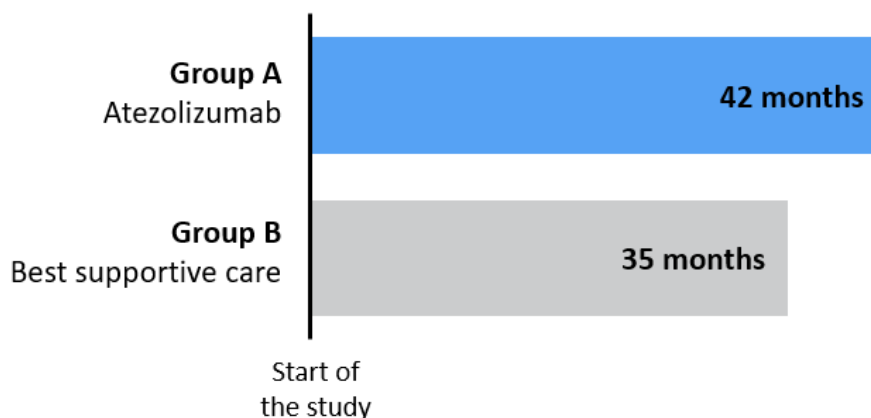
**Question 2:** In people with **stage II-III A NSCLC** regardless of the presence of **PD-L1 on their tumour cells**, how much time was there between the start of atezolizumab treatment and the cancer coming back, new NSCLC being found, or death occurring?

Researchers looked at how much time there was before the NSCLC came back after surgery, new NSCLC was found, or death occurred in people with **stage II-III A NSCLC** in the **atezolizumab** and **BSC group**. This information was collected for both groups from October 2015 until January 2021.

Results were collected and analysed for 442 people in the **atezolizumab group** and 440 people in the **BSC group**.

- In the **atezolizumab group**, it took an average of **42 months**. In some people it took longer and in others it happened sooner than 42 months.
- In the **BSC group**, it took an average of **35 months**. In some people it took longer and in others it occurred sooner than 35 months.

**On average, how much time was there between the start of treatment and the cancer returning or new NSCLC being found in people with Stage II-III A NSCLC?**



This information was collected from October 2015 until January 2021.

- In the **atezolizumab group**, the cancer came back, new NSCLC was found, or death occurred in 173 out of 442 people (39%) with stage II-III A NSCLC.
- In the **BSC group**, the cancer came back, new NSCLC was found, or death occurred in 198 out of 440 people (45%) with stage II-III A NSCLC.

**Question 3:** In people with **stage IB-III A NSCLC** regardless of any **PD-L1 on their tumours**, how much time was there between the start of atezolizumab treatment and the cancer coming back, new NSCLC being found, or death occurring?

Researchers looked at how much time there was before the NSCLC came back after surgery or new NSCLC was found in people with **stage IB-III A NSCLC** in the **atezolizumab group** and the **BSC group**. This information was collected from all the people in both groups from October 2015 until January 2021.

Results were collected and analysed for 507 people in the **atezolizumab group** and 498 people in the **BSC group**.

- In the **atezolizumab group**, the average time **could not be calculated** because at the time these results were analysed, not enough people (50% or more) had their cancer come back, got new NSCLC, or had died.
- In the **BSC group**, it took an average of **37 months**. In some people it took longer and in others it occurred sooner than 37 months.

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see section 8).

## 5. What were the side effects?

Side effects are medical problems (such as feeling dizzy or getting a rash) that may happen during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments in the study.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to very serious.
- Side effects can be different from person to person.
- It is important to be aware that the side effects reported here are from this one study. Therefore, the side effects shown here may be different from those seen in other studies or those that appear on the medicine leaflets.
- Serious and common side effects are described in the next sections.

The safety results shown in this section are for all the people who took the medicines in the study. Results were collected and analysed for 495 people in the **atezolizumab group** and 495 people in the **BSC group**.

### Serious side effects

A side effect is considered 'serious' if it is life-threatening, needs hospital care, or causes lasting problems.

- In the **atezolizumab group**, 37 out of 495 people (7%) had a serious side effect thought to be related to atezolizumab.

Some people in the study died due to side effects that were related to study treatment:

- 4 out of 495 people (less than 1%) in the **atezolizumab group** died.
- 0 out of 495 people (0%) in the **BSC group** died (people in the group that did not receive any study medicine).

## Most common side effects

The most common side effects related to the study medicine are shown in this table – these are the side effects reported by at least 5% of people (5 out of 100) in the **atezolizumab group**. Some people had more than one side effect.

Most common side effects reported in this study	Group A Atezolizumab (495 people in total)
Low levels of hormones made by the thyroid	11% (53 out of 495)
Itching	9% (43 out of 495)
Rash	8% (40 out of 495)
Liver, heart or kidney damage – shown by higher levels of something called ‘AST’ in the blood	7% (37 out of 495)
Liver damage – shown by higher levels of something called ‘ALT’ in the blood	7% (36 out of 495)
High levels of hormones made by the thyroid	6% (29 out of 495)
Fever	5% (27 out of 495)
Joint pain	5% (26 out of 495)

- In the **atezolizumab group**, 90 out of 495 people (18%) decided to stop receiving atezolizumab because of side effects.

## Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 8.

## 6. How has this study helped research?

The information presented here is from one study of 1005 people with stage IB-III A NSCLC. These results helped researchers learn more about treatment with atezolizumab after successful surgery and chemotherapy in these people.

Overall, this study showed that:

- 1) In the people with **stage II-III A NSCLC and PD-L1 on their tumours** who were given atezolizumab after chemotherapy following surgery, it took longer for the cancer to come back, new NSCLC to develop, or death to occur than in people who had BSC after chemotherapy following surgery. In people with **stage II-III A NSCLC regardless of any PD-L1 on their tumours** who were given atezolizumab after chemotherapy

following surgery, it also took longer for the cancer to come back, new NSCLC to develop, or death to occur compared with people who had BSC after chemotherapy following surgery.

- 2) More people who were given atezolizumab had serious side effects than those who had BSC.
- 3) The people in this study did not have any new side effects that had not been seen before in people who took atezolizumab in other studies.

When the information from this study is analysed again after more time has passed, we may learn more about whether atezolizumab works better than BSC at stopping NSCLC from coming back after surgery, new NSCLC from forming, or death occurring in people with **stage II-IIIa NSCLC and PD-L1 on their tumours, stage II-IIIa NSCLC regardless of any PD-L1 on their tumours**, and in those with **stage IB-IIIa NSCLC regardless of any PD-L1 on their tumours**.

## 7. Are there plans for other studies?

Other studies looking at the safety and effects of atezolizumab in people with lung cancer are continuing or will be starting soon. These studies are looking at the use of atezolizumab in different ways, for example:

- Together with other treatments
- Given before surgery for NSCLC
- Given to people as the first treatment for NSCLC that has spread to other parts of the body

## 8. Where can I find more information?

You can learn more about this study on the websites listed below:

- <https://clinicaltrials.gov/ct2/show/NCT02486718>
- <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003205-15>
- <https://forpatients.roche.com/en/trials/cancer/lung-cancer/study-to-assess-safety-and-efficacy-of-atezolizumab--mpdl3280a--.html>

If you want to find out more about the results of this study, the full title of the paper we described here is: “Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIa non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial”. The authors of the scientific paper are Enriqueta Felip, Nasser Altorki, Caicun Zhou, Tibor Csőszi, Ihor Vynnychenko, and others. The paper is published in *The Lancet* and can be accessed with a subscription by visiting: [https://doi.org/10.1016/S0140-6736\(21\)02098-5](https://doi.org/10.1016/S0140-6736(21)02098-5).

## Who can I contact if I have questions about this study?

If you have any questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – <https://forpatients.roche.com/en/trials/cancer/lung-cancer/study-to-assess-safety-and-efficacy-of-atezolizumab--mpdl3280a--.html>.
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

### **Who organised and paid for this study?**

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This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland and Genentech Inc, a member of the Roche Group, who have their headquarters in South San Francisco, California.

### **Full title of the study and other identifying information**

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The full title of this study is: “A Phase III, Open-Label, Randomized Study to Investigate the Efficacy And Safety of Atezolizumab (anti-PD-L1 antibody) Compared With Best Supportive Care Following Adjuvant Cisplatin-Based Chemotherapy in Patients With Completely Resected Stage IB-IIIA Non-Small Cell Lung Cancer”.

The study is known as ‘IMpower010’.

- The protocol number for this study is: GO29527.
- The ClinicalTrials.gov identifier for this study is: NCT02486718.
- The EudraCT number for this study is: 2014-003205-15.