Summary of Clinical Trial Results

A study to look at obinutuzumab with atezolizumab plus lenalidomide in people with 'follicular lymphoma'

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 and
- people who took part in the study.

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

The study started in January 2016 and finished in October 2020. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. 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

Glossary

- G = obinutuzumab
- atezo = atezolizumab
- len = lenalidomide

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about follicular lymphoma, a type of non-Hodgkin lymphoma, and the combination of study medicines.

Key information about this study

- This study was done to look at how effective and safe the study treatment was in people with a type of blood cancer called follicular lymphoma, who had already received other treatment(s) for this type of cancer before this study took place.
- In this study, all patients were given all of the study medicines. Patients were given a combination of obinutuzumab (G), atezolizumab (atezo) and lenalidomide (len).
- All the medicines given in this study are used already for the treatment of cancer.
- In this study, 38 patients received treatment in two countries: France and the USA.
- The main finding was that the combination of G plus atezo with len reduced the number of cancer cells in the body of most of the patients who took part in the study.
- The safety profile of this drug combination is similar to what was already known about the individual drugs.

1. General information about this study

Why was this study done?

Non-Hodgkin lymphoma is a type of cancer that starts in white blood cells called lymphocytes, which help protect the body from infection. Lymphocytes become abnormal and are then unable to fight infections. The abnormal lymphocytes tend to collect in lymph nodes and the spleen, causing them to swell and form cancerous tumours. Patients with non-Hodgkin lymphoma are usually given a treatment called immunochemotherapy. Immunochemotherapy uses medicines that help the body's own immune system to kill the cancer cells, together with chemotherapy.

However, many patients are not successfully treated with the available medicines, so studies are being done to look at different combinations of treatment. All the medicines that were given to patients in this study are already used to treat cancer and have already been tested on their own or in other combinations. This study looked at a new combination of immunotherapy with chemotherapy for one of the most common types of non-Hodgkin lymphoma, follicular lymphoma.

What were the study medicines?

This study looked at 3 medicines:

- obinutuzumab (G)
    - G (also known as GAZYVA®/GAZYVARO®) is a medicine that is already used as part of the treatment for patients who have not yet received treatment for follicular lymphoma or who have advanced follicular lymphoma and did not respond to, or their disease progressed during or up to six months after, previous treatment with another drug called rituximab. G is also used as a

treatment for patients with another type of blood cancer called chronic lymphocytic leukaemia.

- atezolizumab (atezo)
    - atezo (also known as TECENTRIQ®) is a medicine that is used as part of the treatment for lung cancer, bladder cancer, a specific type of breast cancer (called triple-negative breast cancer), a type of skin cancer called melanoma, and liver cancer.
- lenalidomide (len)
    - len (also known as Revlimid®) is a medicine that is used as part of the treatment for several blood cancers: follicular lymphoma, multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma, and marginal zone lymphoma.

What did researchers want to find out?

- Researchers did this study to see how well the specific combination of these medicines worked (see section 4 "What were the results of the study?").
- They also wanted to find out how safe the combination of medicines was by checking how many patients had side effects when taking the medicines during this study (see section 5 "What were the side effects?").

The main questions that researchers wanted to answer were:

1. Did patients' tumours get smaller or disappear after taking the study medicines?
2. What side effects did patients have when taking the study medicines?

What kind of study was this?

This was a 'Phase 1b/2' study, which means that combinations of these medicines had been tested in some people with or without follicular lymphoma before this study. In this study, people with follicular lymphoma took G with atezo plus len – this was to find out if this specific combination worked and was safe in these patients.

This study was 'open-label', which means that everyone involved in the study knew which medicines were given to each patient.

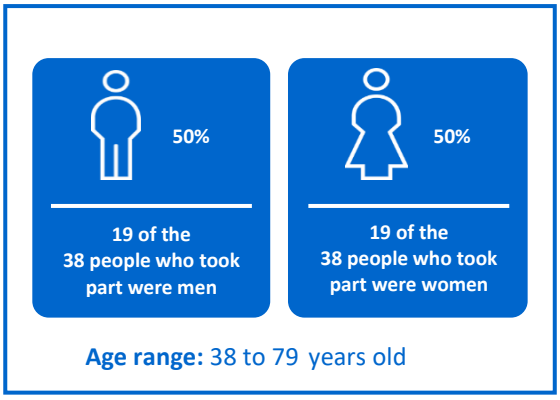
When and where did the study take place?

The study started in January 2016 and finished in October 2020. This summary was written after the study ended.

The study took place at 14 centres across two countries. The countries were France and the USA.

2. Who took part in this study?

This study included 38 people with follicular lymphoma. People who took part were aged 18 years or above.



People could not take part in the study if they met the following criteria (among others):

- had a more aggressive type of follicular lymphoma
- had cancer that had spread to the brain or spinal cord.

3. What happened during the study?

During the study, every patient received G with atezo plus len:

- G was given as an infusion into the vein on Day 1, 8 and 15 during the first round of treatment (each round was 28 days) and on Day 1 for the following five rounds of treatment. This infusion was repeated for a total of six rounds of treatment.
- Atezo was given as an infusion into the vein on Day 1 and 15 of the second round of treatment and on Day 1 and 15 for each of the remaining rounds of treatment. This infusion was repeated for a total of five rounds.
- Len was given by mouth on Days 1 to 21 for a total of six rounds of treatment.

Patients who responded to the initial six rounds of treatment then received G with atezo plus len for a further 24 months:

- G was given on Day 1 every two months.
- Atezo was given on Days 1 and 2 every month.
- Len was given on Days 1 to 21 of each month for the first 12 months only.

4. What were the results of the study?

Question 1: Did patients' tumours get smaller or disappear after taking the study medicine?

Researchers looked at how many patients responded to their study treatment, in other words, had their cancer completely disappeared or got smaller. The researchers used a type

of X-ray called a CT scan to see if tumour(s) had got smaller in size. Not all the patients could be included in the analysis.

A total of 25 out of 32 patients (78%) with follicular lymphoma responded to their study treatment of G with atezo plus len:

- Two of these patients had an improvement in their cancer (i.e. the tumour got smaller) and 23 of them showed no signs of cancer based on their response to treatment as shown by the test described above. In other words, 23 patients experienced a 'complete response'.
- Having a complete response does not necessarily mean that the patient is cured. It just means that after treatment, no sign of disease can be seen.

5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happen during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments that patients received in the study.
- Not all the people in this study had all the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- Serious and common side effects are listed in the following sections.

Serious side effects

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

During this study, 18 out of 38 patients (47%) had at least one serious side effect:

- The most common serious side effects were infections and abnormal growth of cells.

During the study, 11 out of 38 people (29%) stopped taking their medicine because of side effects.

Most common side effects

The most common side effects are shown in the following table – these are the three most common side effects experienced by patients in the study.

Most common side effects reported in this study	**People taking G-atezo-len** (38 people total)
Diarrhoea	58% (22 out of 38)
Low white blood cell number	45% (17 out of 38)
Constipation	40% (15 out of 38)

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 a single study of 38 people with follicular lymphoma. These results helped researchers to learn more about follicular lymphoma and this drug combination of G plus atezo with len.

No single study can tell us everything about the risks and benefits of a medicine. 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.**

7. Are there plans for other studies?

At the time of writing this summary, no more studies looking at this combination of medicines are planned at the current time.

8. Where can I find more information?

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

- https://clinicaltrials.gov/ct2/show/results/NCT02631577
- https://www.clinicaltrialsregister.eu/ctr-search/trial/2015-002467-42/results
- https://forpatients.roche.com/en/trials/cancer/non-hodgkins-lymphoma/a-study-evaluating-the-safety-and-efficacy-of-atezolizu-37082.html

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

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/trials/cancer/non-hodgkins-lymphoma/a-study-evaluating-the-safety-and-efficacy-of-atezolizu-37082.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?

This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is: "A Study Evaluating the Safety and Efficacy of Atezolizumab in Combination With Obinutuzumab Plus Lenalidomide in Patients With Relapsed or Refractory Follicular Lymphoma".

The study is known as 'BO29562'.

- The protocol number for this study is: BO29562.
- The ClinicalTrials.gov identifier for this study is: NCT02631577.
- The EudraCT number for this study is: 2015-002467-42.