

Clinical Trial Results – Layperson Summary

A study to look at whether bemnifosbuvir reduced the amount of virus in people with COVID-19 who were not hospitalised compared with a ‘placebo’ – and how safe this medicine was

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 (September 2022). More information may now be known.

The study started in February 2021 and finished in October 2021 after two planned study groups (A and B). 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. The results from this study may be different from other studies with the same medicine.

- 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.

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Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about COVID-19 and the study medicine.

Key information about this study

- This study was done to test whether bemnifosbuvir could be a safe and effective treatment for people with COVID-19 who were not hospitalised.
- In this study, people were given either the study medicine (called ‘bemnifosbuvir’) or a placebo – it was decided by chance which treatment each person was given.
- This study included 104 people in 6 countries.
- The main finding was that taking bemnifosbuvir did not reduce the amount of virus in the nose and throat better than placebo.
- No people taking bemnifosbuvir or placebo had serious side effects.
- The study stopped after two groups because the study questions had been answered – it was decided that more groups were not needed.

1. General information about this study

Why was this study done?

COVID-19 is a common illness caused by infection with the SARS-CoV-2 virus. It can cause symptoms such as cough, fever, sore throat, being sick and loss of smell or taste.

Most people who catch COVID-19 have mild symptoms, but some people can get seriously ill and may need to be hospitalised. Older people and people with medical conditions (for example, heart disease or cancer) are at higher risk of severe illness.

New medicines are needed to treat COVID-19 and to help stop people from getting seriously ill or dying.

Bemnifosbuvir is a new antiviral medicine (a medicine that treats infections caused by a virus) that may be able to treat COVID-19. This study was done to find out if bemnifosbuvir can be used to treat mild or moderate COVID-19 in people who are not hospitalised. Researchers also wanted to find out how safe bemnifosbuvir was.

What was the study medicine?

A medicine called ‘bemnifosbuvir’ (also called AT-527) was the focus of this study.

- You say this as ‘Bem – nee – foz – buh – veer’.
- Bemnifosbuvir works by stopping the virus that causes COVID-19 from multiplying inside the body.
- This may mean that bemnifosbuvir could help people with COVID-19 feel better and stop their illness getting worse.
- Bemnifosbuvir was tested at different doses.

Bemnifosbuvir was compared to a ‘placebo’.

- You say this as ‘plah – see – bo’.
- The placebo looked the same as bemnifosbuvir but did not contain any real medicine. This means it had no medicine-related effect on the body.
- Researchers compared the study medicine to a placebo so they could show which benefits or side effects are actually caused by the medicine.

What did researchers want to find out?

- Researchers did this study to compare the study medicine (bemnifosbuvir) with a placebo – to see how well the study medicine worked (see section 4 “What were the results of the study?”).
- They also wanted to find out how safe the medicine was – by checking how many people had side effects when taking each of the medicines during this study (see section 5 “What were the side effects?”).

The main question that researchers wanted to answer was:

1. How well did bemnifosbuvir reduce the amount of virus being produced in the nose and throat of people with mild or moderate COVID-19 – who were not hospitalised?

Other questions that researchers wanted to answer included:

2. What were the side effects of bemnifosbuvir in people with mild or moderate COVID-19 – who were not hospitalised?

What kind of study was this?

This study was a ‘Phase 2’ study. This means that bemnifosbuvir had been tested in a number of people without COVID-19 before this study. In this study, people with mild or moderate COVID-19 either took bemnifosbuvir or a placebo – this was to find out if bemnifosbuvir reduced the amount of virus being produced in the nose and throat of people with COVID-19 who were not hospitalised.

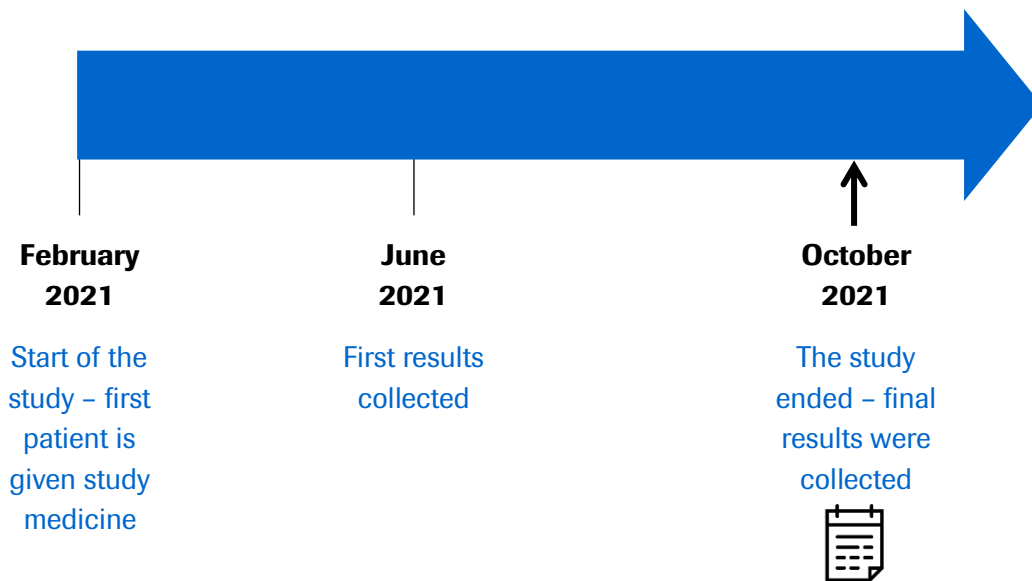
The study was ‘randomised’. This means that it was decided by chance which of the medicines people in the study would have – like tossing a coin.

This was a ‘double-blind’ study. This means that neither the people taking part in the study nor the study doctors knew which of the study medicines people were taking.

‘Blinding’ of a study is done so that any effect seen from the medicine is not due to something people expected to happen – if they had known which medicine they were taking.

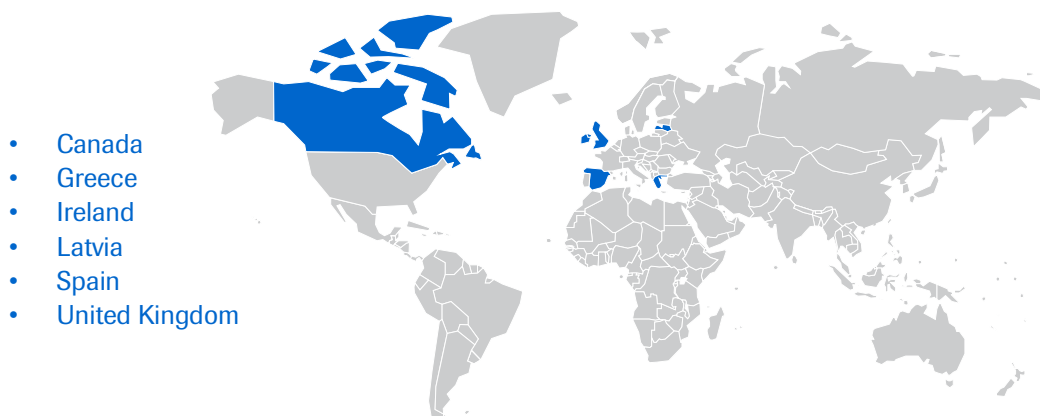
When and where did the study take place?

The study started in February 2021 and finished in October 2021. This summary was written after the study had ended.



This symbol on the timeline (📅) shows when the information shown in this summary was collected – after 8 months (October 2021).

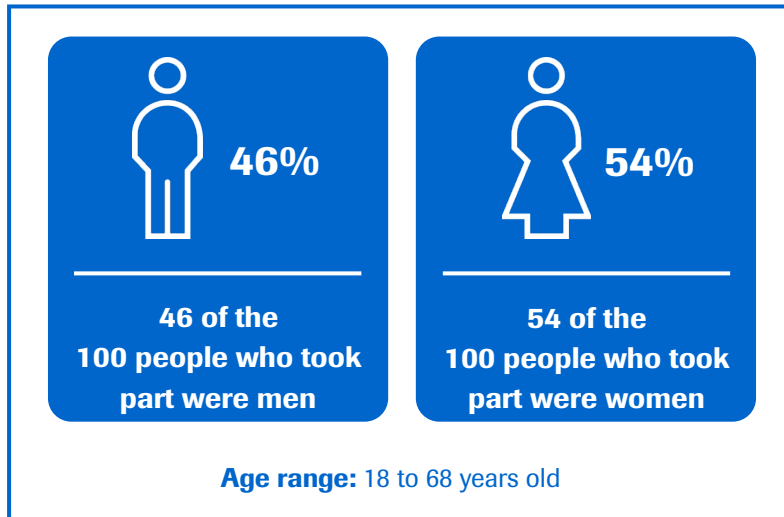
The study took place at 12 study centres – across 6 countries (Canada, Greece, Ireland, Latvia, Spain and the United Kingdom). The following map shows the countries where this study took place.



2. Who took part in this study?

In this study, 104 people with mild or moderate COVID-19 took part. 4 people were selected to take part in the study but did not take any treatment – these people are not included in the results below.

People who took part in the study were between 18 and 68 years of age. 46 of the 100 people who were given treatment (46%) were male and 54 of the 100 people (54%) were female.



People could take part in the study if they:

- were over 18 years old
- had a positive test for COVID-19
- had mild or moderate symptoms of COVID-19 that had started no more than five days before the start of the study.

People could not take part in the study if they:

- had symptoms of severe COVID-19 needing hospitalisation
- had been treated with any other medicine for COVID-19 in the three months before the start of the study
- were pregnant or breastfeeding.

3. What happened during the study?

During the study, people were selected by chance to get 1 of 2 treatments. The treatments were selected at random – by a computer.

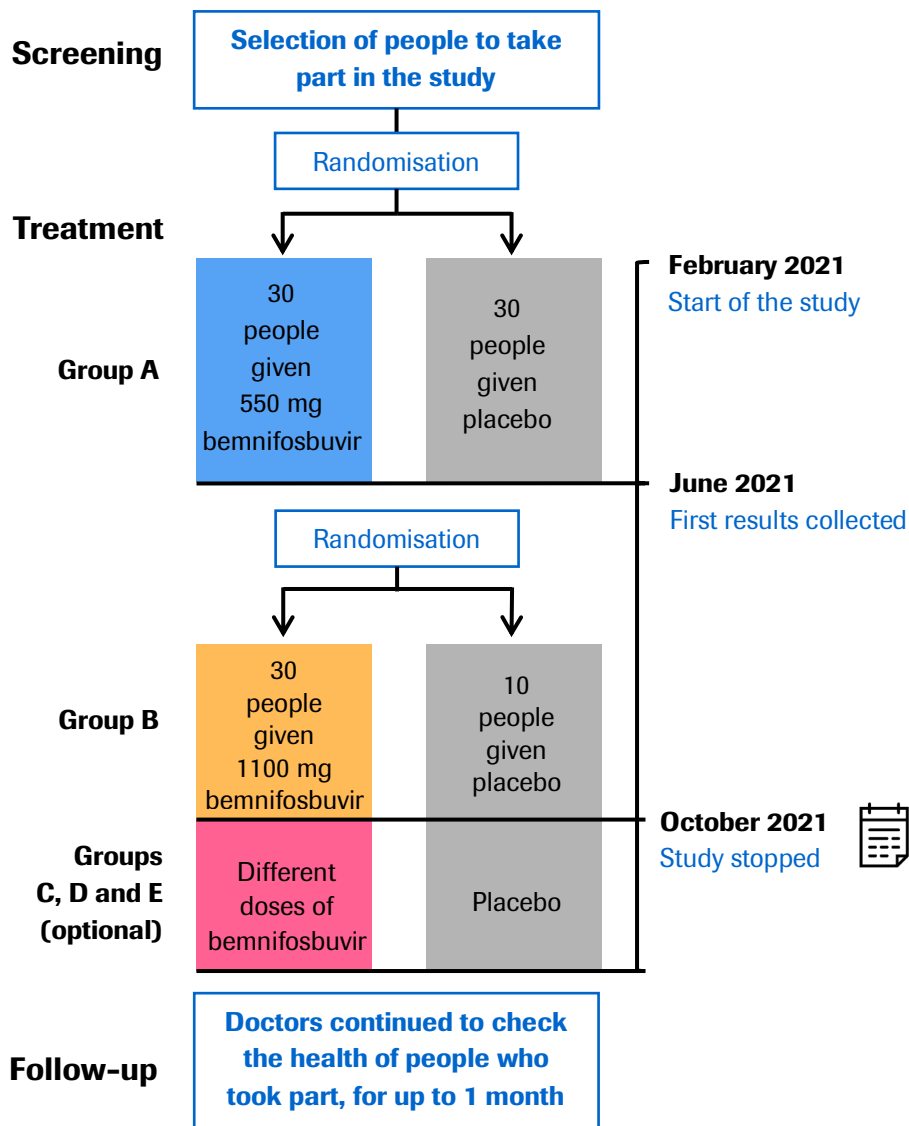
The treatment groups were:

- **Bemnifosbuvir** (the study medicine) – tablet taken by mouth twice a day for 5 days.
- **Placebo** – tablet taken by mouth twice a day for 5 days.

In the first group of people in the study, for every person selected to get bemnifosbuvir, one person was selected to get placebo.

After 4 months, a second group of people was added to the study. People in this group were treated with a different dose of bemnifosbuvir or placebo. In this group, for every three people selected to get bemnifosbuvir, one person was selected to get placebo. The results from people taking bemnifosbuvir in this group were compared with the results from all the people who were given placebo in the study. This helped reduce the total number of people needed in the study to answer the researchers' questions.

After people finished taking their study medicine, they were asked to go back to their study centre for more visits – to check their overall health. The study flowchart shows all stages planned for the study (Groups A and B), as well as three optional groups (Groups C, D and E). The symbol (📅) shows the point where the study was finished, after Group B. Optional Groups C, D and E were not started.



4. What were the results of the study?

How well did bemnifosbuvir reduce the amount of virus being produced in the of nose and throat of people with mild or moderate COVID-19 – who were not hospitalised?

Researchers looked at the amount of virus in the nose and throat of people with COVID-19 before and after they had taken the study medicine – to see if bemnifosbuvir could reduce the amount of virus better than placebo.

Bemnifosbuvir did not reduce the amount of virus in people's nose and throat better than placebo:

- People who were given 550 mg bemnifosbuvir (Group A) had a similar amount of virus in their nose and throat after treatment as people who were given placebo.
- People who were given 1100 mg bemnifosbuvir (Group B) also had a similar amount of virus in their nose and throat after treatment as people who were given placebo.

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

5. What were the side effects?

Side effects (also known as 'adverse reactions') are unwanted medical problems (such as a headache) that 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.

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, no people in any group had serious side effects.

There were no deaths reported in this study.

During the study, some people decided to stop taking their medicine because of side effects:

- In Group A (550 mg bemnifosbuvir), no people stopped taking their medicine because of side effects.
- In Group B (1100 mg bemnifosbuvir), 5 out of 30 people (17%) stopped taking their medicine because of side effects.
- In the placebo group, 1 person out of 40 (3%) stopped taking their medicine because of side effects.

Most common side effects

During this study, around 12 out of every 100 people (12%) had a side effect that was not considered serious:

- In Group A (550 mg bemnifosbuvir), around 7% had a side effect that was not considered serious.
- In Group B (1100 mg bemnifosbuvir), around 17% had a side effect that was not considered serious.
- In the placebo group, around 13% had a side effect that was not considered serious.

The most common side effects are shown in the following table – these are the side effects that occurred in at least 5% of the people in any group who took part in this study.

Most common side effects reported in this study	People taking bemnifosbuvir 550 mg (Group A) (30 people total)	People taking bemnifosbuvir 1100 mg (Group B) (30 people total)	People taking placebo (40 people total)
Being sick (vomiting)	0% (0 out of 30)	17% (5 out of 30)	0% (0 out of 40)
Feeling sick (nausea)	0% (0 out of 30)	10% (3 out of 30)	0% (0 out of 40)

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 104 people with mild or moderate COVID-19 who were not hospitalised. These results helped researchers learn more about the safety of bemnifosbuvir and its effect on virus levels in the nose and throat of people with mild or moderate COVID-19.

Key findings from this study:

- The main finding was that taking the study medicine, bemnifosbuvir did not reduce the amount of virus in the nose and throat of people with COVID-19 better than placebo.
- No serious side effects happened in people taking bemnifosbuvir or placebo.
- The most common side effects in people taking the highest dose of bemnifosbuvir tested in the study (1100 mg) were being sick (vomiting/throwing up) and feeling sick (nausea). These side effects were not observed in Group A (550 mg bemnifosbuvir).

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. The results from this study may be different from other studies with the same medicine.

- 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?

Yes, Atea Pharmaceuticals is planning more studies looking at bemnifosbuvir for COVID-19, using the 550 mg twice a day dose.

Although bemnifosbuvir did not seem to reduce virus levels in the nose and throat of people with COVID-19 in this small study, more studies are needed to confirm these findings – and to see if bemnifosbuvir can reduce virus levels in other parts of the body and whether it is effective in treating patients with COVID-19.

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/NCT04709835>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-005366-34/IE>
- <https://forpatients.roche.com/en/trials/infectious-diseases/covid-19-pneumonia/study-to-evaluate-the-effects-of-at-527-in-non-hospital-29576.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/infectious-diseases/covid-19-pneumonia/study-to-evaluate-the-effects-of-at-527-in-non-hospital-29576.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.

If you have any questions about future development of bemnifosbuvir for the treatment of COVID-19, please contact Atea Pharmaceuticals at ateaclinicaltrials@ateapharma.com or visit <https://clinicaltrials.gov> for more information on current and future trials.

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, and Atea Pharmaceuticals, Inc. who have their headquarters in Boston, USA.

Full title of the study and other identifying information

The full title of this study is: “A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Antiviral Activity, Safety, Pharmacokinetics, and Efficacy of RO7496998 (AT-527) in Non-Hospitalized Adult Patients with Mild or Moderate COVID-19”.

The study is known as ‘MOONSONG’.

- The protocol number for this study is: WV43042.
- The ClinicalTrials.gov identifier for this study is: NCT04709835.
- The EudraCT number for this study is: 2020-005366-34.