

## Summary of Clinical Trial Results

### A study to find out how safe is it to give people with asthma a new medicine called MTPS9579A

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).

This summary is written for:

- Members of the public
- People who took part in the study

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

The study started in November 2019 and finished in January 2022. 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 answer important questions about asthma and the study medicine, “MTPS9579A”.

## Key information about this study

- This study was done to find out if MTPS9579A was safe and tolerable for people with asthma.
- In this study, people with asthma were given either the medicine being studied (MTPS9579A) or a placebo – it was decided by chance which treatment each person was given.
- This study included 27 people in one country.
- The main finding was that researchers did not find any serious side effects that were thought to be caused by the treatment (MTPS9579A or placebo).
- There were no non-serious side effects thought to be caused by the treatments (MTPS9579A or placebo) either.
- The amount of MTPS9579A in the body increased when the dose was increased.
- MTPS9579A showed some activity in the nose, but it was not active in the lungs.
- The number of people with anti-MTPS9579A antibodies did not increase after treatment.

## 1. General information about this study

### Why was this study done?

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Asthma is a disease of the airways leading to the lungs. Patients with asthma may have coughing, wheezing, and difficulty breathing.

Approximately 300 million people in the world have asthma. About 420,000 people in the world die each year because of asthma. Millions of others have to miss school or work or have to go to the hospital because of their asthma.

Several different types of medicines are used to control asthma. However, many patients continue to have asthma that cannot be controlled by any available medicine.

Researchers who study asthma know that there are different triggers for asthma, and there are different types of asthma. For some asthma subtypes, the disease is driven by immune cells and proteins released by these immune cells.

“Mast cells” are a type of immune cells found in the lungs (and other places). Mast cells release a protein called “tryptase” (and other substances) into the lungs in response to allergic or inflammatory triggers.

Tryptase promotes:

- Hyper-responsiveness: The narrowing of the airways in people prone to asthma – in response to stimuli that would produce little or no effect in healthy people.
- Bronchoconstriction: The tightening of muscles in the airways leading to the lungs that cause coughing, wheezing, and shortness of breath.
- Amplification of mast cell degranulation: The presence of tryptase in the surroundings causes other mast cells to release tryptase as well.

MTPS9579A is a new medicine that may be useful for reducing tryptase and helping people who have asthma.

This study was done to find out if MTPS9579A was safe enough to give to people who have asthma.

### What was the medicine being studied?

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This study looked at the study medicine and a placebo:

#### **MTPS9579A**

- This medicine is an antibody that binds to tryptase and stops it from functioning – it reduces the amount of active tryptase but not the total tryptase levels.
- It is given through intravenously (IV) through the vein, and may reverse the symptoms of asthma in patients.
- It has been tested in healthy people and found to be safe enough to be given to healthy people at the tested dose levels.

## Placebo

- Everyone in this study got a treatment. The treatment contained the study medicine (MTPS9579A) or a placebo.
- The placebo looked like the real medicine but did not contain any medicine. This means it had no medicinal effects on the body.
- Researchers compared treatments with MTPS9579A to the placebo – so they could show which benefits or side effects of the treatment were actually caused by MTPS9579A.

## What did researchers want to find out?

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

1. Was MTPS9579A safe for people who had asthma?
2. What was the concentration of MTPS9579A in the body at different time points?
3. Does MTPS9579A affect the level of tryptase in the airway?
4. Does the human body make any antibodies when exposed to MTPS9579A?

## What kind of study was this?

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Here are some of the words used to describe this study.

- **Phase 1 study**  
This was a “Phase 1” study, which means that this was one of the early studies for MTPS9579A. A small number of healthy people (without asthma) were treated with MTPS9579A in other Phase 1 studies. In this Phase 1 study, the study medicine was given to people who had asthma.
- **Randomized study**  
A computer randomly decided who joined which treatment group. Researchers and people in the study had no control over who got MTPS9579A and who got placebo.
- **Placebo-controlled study**  
Some people in the study got treatments with a placebo. This allowed researchers to compare how people reacted to treatments with the real medicine and with no medicine. That made it a “placebo-controlled study”.
- **Observer-blinded study**  
The researchers who were collecting results did not know who was getting the medicine and who was getting the placebo. This made it an observer-blinded study, and was another way to reduce unfairness (bias) in the study.

## When and where did the study take place?

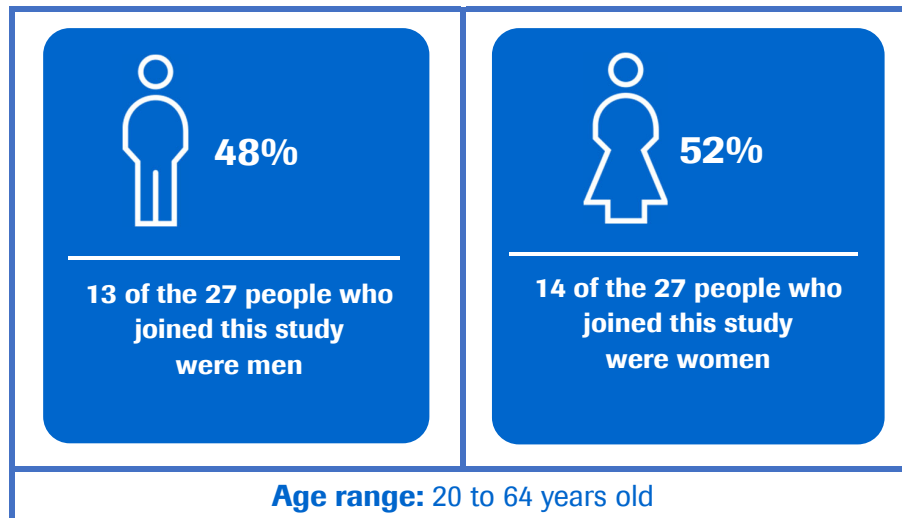
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The study started in November 2019 and finished in January 2022. This summary was written after the study had ended.

The study took place at six study centers in the United Kingdom.

## 2. Who took part in this study?

Twenty-seven people who used asthma treatments –inhaled corticosteroids (**ICS**) and another treatment (**second controller**) – took part in this study.



**People could take part in the study if they met all of the conditions below:**

- They were between 18 and 65 years of age.
- They weighed at least 40 kg and met a certain height-weight ratio (body mass index of 18 to 35 kg/m<sup>2</sup>).
- They had asthma disease conditions that were required for joining the study.

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

- They had a history of any one of several medical conditions not permitted in this study.

## 3. What happened during the study?

During the study, people were selected by chance to get one of 3 treatments.

The treatment groups were:

- Placebo (9 people).
- MTPS9579A 300 mg (9 people).
- MTPS9579A 1800 mg (9 people).

Procedures were done on people at several time points before and after treatment.

- Bronchoscopy: Doctors passed a thin tube (bronchoscope) through the nose or mouth, down the throat and into the lungs – to see the lungs and airways.
- Bronchosorption: Doctors used instruments to look at the airway and collect samples from the lungs (bronchial mucosal lining fluid) for analysis.
- Nasosorption: Doctors swabbed the inside of the nose to collect fluid (nasal mucosal lining fluid) for analysis.

### **Day1**

One to five days after the bronchoscopy, people in the study got one treatment of a single dose of MTPS9579A or placebo, delivered through an IV.

### **Follow-up**

About 3 weeks after treatment, the people in the study returned to the clinic for another bronchoscopy.

There were other phone calls and visits to the clinic – to monitor side effects, collect blood and nasosorption samples – on different days. These ended on Day 120.

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

### **Question 1: Was MTPS9579A safe for people who had asthma?**

Researchers looked at side effects in people who were given the different treatments. Nobody in any treatment group had a side effect or a serious side effect thought to be caused by the treatment.

One person in the study had a heart attack. Researchers did not think it was caused by the study treatment.

Researchers thought that MTPS9579A was safe and well tolerated for people with asthma in this study – at the doses tested.

### **Question 2: What was the concentration of MTPS9579A in the body at different time points?**

Another piece of information that researchers collected was the concentration of MTPS9579A in blood at different times.

Results showed that:

- The concentration of MTPS9579A in blood was proportional to the dose that was given to the person.
- After reaching the highest concentration in the body, the time needed to reach half of this concentration was 12 days for the 300 mg dose level, and 30 days for the 1800 mg dose level.

### **Question 3: Does the MTPS9579A affect the level of tryptase in the airway?**

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Researchers looked at tryptase levels in lung, nose, and blood samples collected before treatment (baseline) – and after dosing.

- The amount of active tryptase in the nose was lower after dosing. Therefore, MTPS9579A was active in the nose.
- The amount of active tryptase in the lungs was not much different after dosing. MTPS9579A did not reduce the active tryptase in the lungs. This suggested that the MTPS9579A was not effective in the lower airway in humans.

### **Question 4: Does the human body make any antibodies when exposed to MTPS9579A?**

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One person out of the 26 people who were tested before treatment had anti-MTPS9579A antibodies. None of the 17 people tested after treatment had anti-MTPS9579A antibodies.

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) that happened 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 and can be different from person to person.
- It is important to be aware that the side effects reported here are from this single study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflet.
- Serious and common side effects are listed in the following sections.

### **Serious side effects**

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

During this study, nobody had any serious side effects that the study doctors thought were caused by the treatments.

One person in the study had a heart attack. Study doctors did not think this was caused by the study treatment.

Twenty-seven people in this study got their treatments. There were no deaths in this study.

### **Most common side effects**

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During this study, nobody got a side effect that was not serious but was thought to be caused by the study medicine.

## Other side effects

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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 27 people with asthma. These results helped researchers learn more about asthma and MTPS9579A.

In the 27 people with asthma, MTPS9579A did not show any side effects or serious side effects thought to be caused by the study medicine. Researchers thought MTPS9579A was safe and tolerable at the two doses tested – for people with asthma in this study.

Researchers found out that MTPS9579A showed some activity in the nose but not in the lungs.

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.

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## 7. Are there plans for other studies?

At the time of writing this summary, the study sponsor stopped the development of MTPS9579A as a treatment for asthma. Results became available from a Phase 2 study that showed MTPS9579A was not effective for the treatment of asthma.

## 8. Where can I find more information?

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

<https://forpatients.roche.com/en/trials/respiratory-disorder/asthma/a-study-to-find-out-how-safe-is-it-to-give-people-with-asthma-a-.html>

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

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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/About.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 organized and paid for this study?**

This study was organized and paid for by Genentech, Inc., South San Francisco, CA, USA. Genentech is part of F. Hoffmann-La Roche Ltd., with headquarters in Basel, Switzerland.

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

The full title of this study is:

A phase 1c, multicenter, randomized, observer-blinded, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of a single dose of MTPS9579A in patients with asthma requiring inhaled corticosteroids and a second controller.

- The protocol number for the study is GA41003.
- The EudraCT number for this study is 2018-003562-14.