

## Summary of Clinical Trial Results

### A study to find out if a new medicine – MTPS9579A – works in people with asthma

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 October 2019 and finished in May 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 many people in several 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.**

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

The people who took part have helped researchers answer important questions about asthma the study medicine, MTPS9579A.

#### Contents of the summary

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## Key information about this study

- This study was done to find out if a new study medicine was useful for controlling asthma.
- People in this study 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 134 people with asthma – from five countries.
- The main finding was that MTPS9579A was not effective for controlling asthma in people in this study.
- Nobody in this study had a serious side effect that study doctors thought was due to the study treatment.
- Seven people (11%) who got placebo and one person (1%) who got MTPS9579A got side effects that were not serious, but study doctors thought they were caused by the study treatments.
- MTPS9579A will no longer be developed for asthma.

## 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. People 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 – called “**controller therapies**”. However, many people 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 encourages the following responses in the body:

- Hyper-responsiveness: The narrowing of the airways in people prone to having 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 – this causes 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 (not yet approved) medicine. It was tested to find out if it may be useful for reducing tryptase and helping people who have asthma.

This study was done to find out if MTPS9579A was effective for controlling asthma in people who used **inhaled corticosteroids (ICS)** and another medicine – a **second controller** for the asthma.

### What was the study medicines?

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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.
- It is given intravenously (IV) – through the vein, and is being tested for its usefulness in reversing the symptoms of asthma in people.
- It has been tested in healthy people and people with asthma – and found to be safe enough to be given 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 treatments with 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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Researchers did this study to compare MTPS9579A with a placebo – to see how well the MTPS9579A 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 and seeing how serious they were (see Section 5 “What were the side effects?”).

### The main question that researchers wanted to answer was :

1. Was MTPS9579A effective for people with asthma – when given on top of other therapies that people were already using?

## What kind of study was this?

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There are several ways to describe this study.

- **Phase 2 study**  
The Phase 2 study was done to find out if the study medicine was effective for people – who had the disease that the medicine was targeting.  
Often times, the study medicine tested in Phase 2 – has already been tested Phase 1 studies – and found to be safe for use in people.
- **Randomized study**  
A computer randomly decided who joined which treatment group. Researchers and people in the study had no control over this.
- **Double-blind study**  
The researchers and people in the study did not know who was getting which treatment. That made this a double-blind study.
- **Placebo-controlled study**  
Some people 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”.

## When and where did the study take place?

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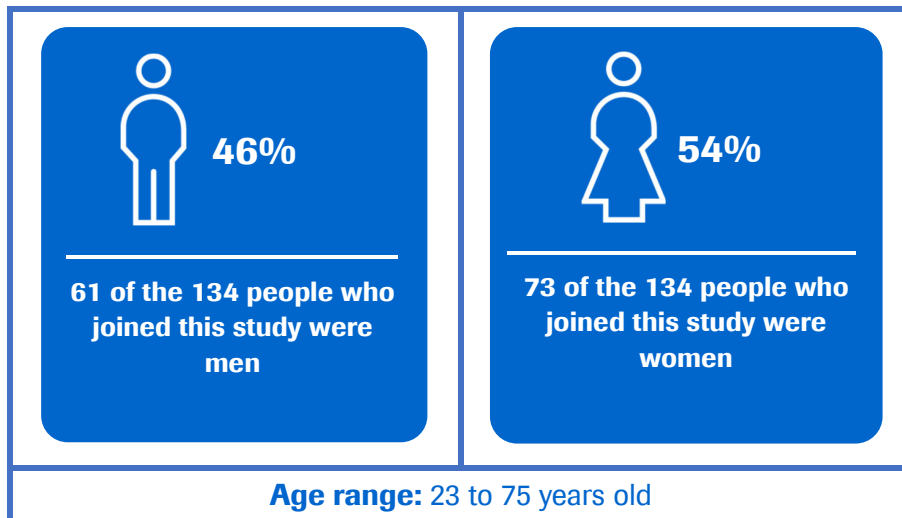
The study started in October 2019 and finished in May 2022. This summary was written after the study had ended.

The study took place at 26 study centers in 5 countries:

- Argentina – 4 study centers
- Germany – 5 study centers
- Peru – 2 study centers
- Poland – 8 study centers
- USA – 7 study centers

## 2. Who took part in this study?

One hundred and thirty-four people who had asthma took part in this study.



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

- They were between the ages of 18 to 75 years.
- They had asthma for at least one year – diagnosed by a doctor.
- They weighed at least 40 kg and had met the required height-to-weight ratio (BMI 18-38 kg/m<sup>2</sup>).
- They took a breathing test (spirometry) and met the requirements for being in this study.
- They were using ICS and a second controller for at least the last 3 months – and with no changes in the last 4 weeks.
- They filled out a questionnaire and had the required score (asthma control questionnaire - ACQ-5).
- They had two or more asthma attacks (exacerbations) in the last 12 months while on ICS “maintenance therapy” – to control their symptoms.
- They demonstrated “know-how” (competence) for their daily responsibilities to be in the study.
- Males with female partners and females on the study agreed to use birth control.

**People could not take part in the study if they met any one of the following conditions:**

- Any health history or current health condition not allowed in this study.
- History of being a heavy smoker or heavy e-cigarette user.
- Current light smoker or light e-cigarette user unwilling to stop for the duration of the study.
- History or current use of controlled substance that could interfere with the study.
- Surgery planned for a date that fell during the study.
- Known sensitivity to any ingredient in the study treatments.
- Starting or changing medications just before or during the study.
- Treatment with blood transfusion or blood products just before or during the study.
- Vaccination with live or changed (attenuated) virus just before or during the study.
- Recent treatment history or plans for treatment during study – using several medicines not allowed in this study.

**3. What happened during the study?**

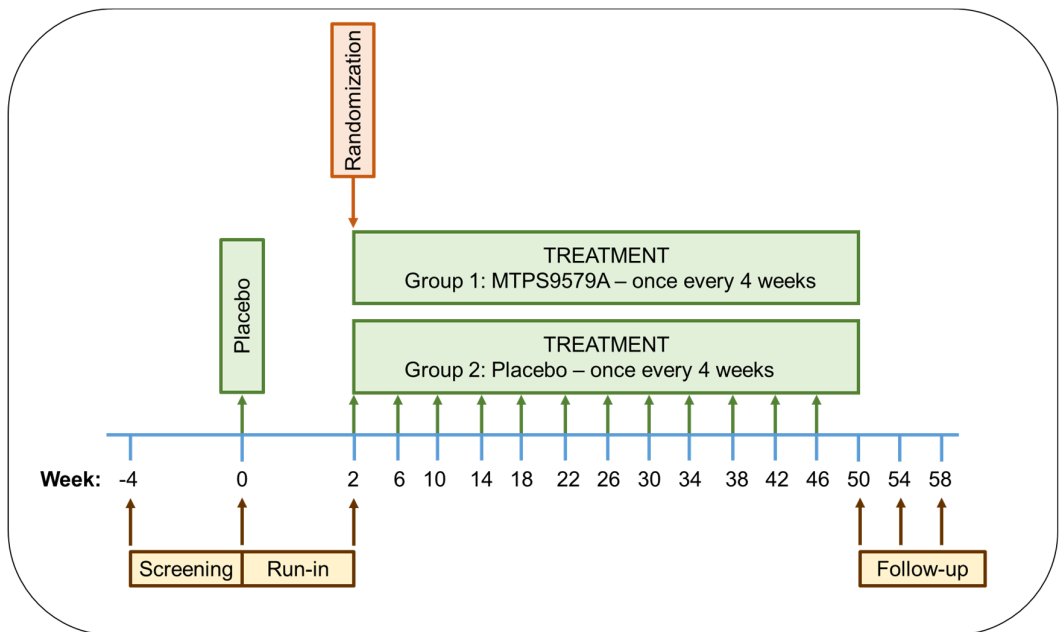
Different study activities happened at different times.

**Screening**

- Week -4 to Week 0: For 4 weeks before the study started, people were “screened” to see if they met the conditions for joining this study.

**Run-in**

- Week 0: Everyone got one dose of placebo treatment.
- Week 2: People were randomized to join either Group 1 or Group 2.



### Treatment

- People visited the study center to get their treatments. Treatment was given once every 4 weeks, starting at Week 2. The last treatment was at Week 46.
- Each treatment was given intravenously (**IV**) using a needle that went into a vein.
- People getting treatments and the study center staff did not know who was getting MTPS9579A and who was getting placebo. That made it “double-blind”.

### Follow-up

- People in the study visited the study center at Week 50 and Week 54 for tests – and to answer questions.
- During Week 58 (or Week 63 for some people in the study), the study staff made phone calls and asked questions.

### Other requirements

- People were required to continue taking their daily treatments of ICS and another controller – during this study.
- They were asked to write (document) their health status in a diary – twice a day.

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

### Question 1: Was MTPS9579A effective for people with asthma – when added on top of other therapies that people were already using?

Researchers looked at the number of **asthma events**. The events were:

- Asthma exacerbation: These were new or worsening symptoms that resulted in an intervention (hospital visit and/or treatments).
- Diary worsening of asthma: These were changes to their health as recorded in their diaries. These included breathing test results, use of medications, and asthma symptoms.

	Placebo	MTPS9579A
<b>Number of people in this treatment group</b>	65	69
<b>Number of people with asthma events</b>	34 (52%)	32 (46%)

- A smaller percentage (46%) of people who got MTPS9579A had asthma events while on the study – in comparison to the placebo group ((52%).
- Researchers did statistical tests to compare these numbers. They found the difference was not statistically significant. That means the difference was not large enough to show that MTPS9579A was better.
- MTPS9579A did not work better than the placebo.

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.

- If they happened in this study, they are described in this summary because the study doctor believed the side effect to be related to the treatments in the study.
- Not all of the people in any one study have all of the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- If side effects are reported in this summary, it is important to be aware that they 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.
- If serious and common side effects happened in this study, they will be 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, nobody reported a serious side effect that researchers thought was caused by the study treatments.

- One person in the placebo group – with a side effect that was not serious but thought to be caused by the treatment – decided to stop the study treatment.
- Two people died while participating in this study. One person from the placebo treatment group died due to COVID-19 pneumonia. Another person in the MTPS9579A treatment group died in an accident. None of these deaths were caused by the study medicine.

### Most common side effects

During this study, 8 people (6%) out of 134 – had side effects – not considered serious, but thought to be caused by the study treatment.

	Placebo	MTPS9579A
<b>Number of people in this treatment group</b>	65	69
<b>Number of people with side effects that were not serious but thought to be caused by the study treatments</b>	7 (11%)	1 (1%)
<b>Side effects:</b>		
Feeling sleepy (somnolence)	2 people (3%)	0
Discoloration at the injection site	1 person (2%)	
Feeling dizzy	0	1 person (1%)
Feeling tired (fatigue)	1 person (2%)	0
Feeling weak (asthenia)	1 person (2%)	0
Fever (increased body temperature)	1 person (2%)	0
Reaction at the injection site	1 person (2%)	0
Red patches on skin (erythema multiform)	1 person (2%)	0
Sweating without a reason (hyperhidrosis)	1 person (2%)	0



## 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 134 people. These results helped researchers learn more about asthma and the study medicine. Researchers learned that MTPS9579A was not effective for controlling asthma – when compared to placebo treatment – in people who were taking ICS and a second controller for their asthma.

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?

At the time of writing this summary, no more studies looking at MTPS9579A were planned for asthma. The medicine did not show improvement for asthma.

## 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/NCT04092582>

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-000795-41/results>

<https://forpatients.roche.com/en/trials/respiratory-disorder/asthma/a-study-to-evaluate-the-efficacy--safety--and-pharmacok-66457.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?**

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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**

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The full title of this study is:

A phase 2a, multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy, safety, and pharmacokinetics of MTPS9579A in patients with asthma requiring inhaled corticosteroids and a second controller.

- The protocol number for this study is GB41149.
- The ClinicalTrials.gov identifier for this study is NCT04092582.
- The EudraCT number for this study is 2019-000795-41.