NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ofatumumab in people with relapsing multiple sclerosis (RMS) who switched from other approved RMS treatments

Thank you!

Thank you to the participants who took part in the clinical trial for **relapsing multiple sclerosis (RMS)**. Every participant helped to learn more about the trial drug **ofatumumab**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: COMB157G23101

Novartis drug studied: ofatumumab, also called **OMB157**

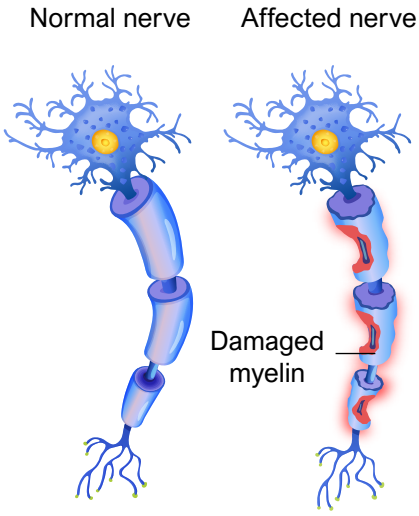
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects of **ofatumumab** in people with relapsing **multiple sclerosis (RMS)** who switched to **ofatumumab** from other approved RMS treatments that did not help control their disease.



Multiple sclerosis (MS) is a condition that affects the brain and spinal cord. In people with MS, the immune system mistakenly attacks the protective coating around the nerves, called myelin. This leads to nerve damage and scar tissue formation or lesions, causing various symptoms. People with **RMS** have new symptoms after a period of improvement or worsening of existing symptoms.

Common symptoms of **MS** are:

- Muscle weakness
- Numbness or tingling
- Vision problems
- Tiredness
- Walking difficulties
- Problems with coordination and balance

Fingolimod and fumarate-based treatments such as dimethyl fumarate, diroximel fumarate are usually given for **RMS**. However, they may not work for everyone.

The trial drug, **ofatumumab**, is already approved in the United States and the European Union for the treatment of **RMS**. It works by reducing the number of immune cells that attack the myelin and causes MS symptoms.

In this trial, researchers wanted to learn about the effects of **ofatumumab** in people who switched from fingolimod or fumarate-based treatments.

Trial drug

ofatumumab also called **OMB157**

Pronounced as

oh-fah-TOO-moo-mab

The trial's purpose was to answer these main questions:

- How many MS relapses did participants who switched to ofatumumab from other approved RMS treatments have in a year?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in July 2020 and ended in March 2025. The trial was designed so that each participant would take part for up to 2 and a half years.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?

562 participants with **RMS** received treatment in this trial – 369 females and 193 males.

Participants' ages ranged from 18 to 59 years. Their average age was 36 years.

The table shows the number of participants by race.

Race

550 White	7 Black or African American	4 American Indian or Alaska Native	1 Native Hawaiian or Other Pacific Islander

562 participants from **27 countries** received treatment. The map below shows the number of participants who took part in each country.

Participants **could take part** in this trial if they:

- Were at least 18 years old
- Had **RMS**
- Received fingolimod or fumarate-based treatments for at least 6 months before this trial
- Had imaging scans that showed new or growing MS lesions while receiving fingolimod or fumarate-based treatments
- Did not have other ongoing immune-related conditions besides MS

What treatments did the participants receive?

The treatment in this trial was:

Ofatumumab: **20 milligrams (mg)**, given as injections under the skin. The injection was given using an auto-injector, which is a pen-like device that delivers the medicine under the skin.

The participants, researchers, and trial staff knew that all participants received ofatumumab treatment.

What happened during this trial?

Before treatment

Up to 2 months

The trial staff checked to make sure the participants could be in this trial.

During treatment

Up to 2 years

A total of **562 participants** received treatment with **ofatumumab** during this trial. They initially received the treatment on Days 1, 7, and 14. After that, they received it once every month until the end of the treatment period.

Ofatumumab
562 participants

Participants received the first **ofatumumab** dose at the clinic and could take the remaining doses at home. After the first dose, participants visited the clinic for check-ups at Month 1, Month 2, Month 3, and then every 3 months until the end of treatment.

After treatment

Until the trial ended

Trial staff checked participants' general health and for any medical problems for up to 6 months after their last dose.

After the trial, participants could continue **ofatumumab** outside of this trial if their doctors thought they were benefiting from it. If they did not continue **ofatumumab** outside of this trial, they had check-ups every 3 months until they either began another treatment or their white blood cells returned to a healthy level.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

How many MS relapses did participants who switched to ofatumumab from other approved RMS treatments have in a year?

The results showed that participants had fewer than 1 relapse per year while receiving **ofatumumab**.

Researchers wanted to find out the number of MS relapses participants had over the course of a year. Trial doctors regularly checked participants for MS symptoms.

A relapse is when MS symptoms get worse or new symptoms appear. The symptoms must last at least 24 hours and cannot be caused by a fever or infection.

To confirm a relapse, trial doctors looked for clear changes in how the nervous system was working. They used the **Expanded Disability Status Scale (EDSS)** to measure these changes.

The EDSS helps doctors understand how MS affects everyday abilities such as walking, balance, coordination, vision, and bladder control. This scale helps to track how symptoms change over time. When possible, relapses were confirmed within 7 days after symptoms began.

Researchers counted how many relapses each participant had during the trial and how long they were in the trial. They used this information to calculate the average number of relapses a participant would have in one year.

They found that participants had about **0.06 relapses per year**. This means most participants had fewer than 1 relapse per year while receiving **ofatumumab**.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the day participants started the trial treatments until 6 months after the last dose.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

A total of **509 out of 562 participants** had adverse events, including serious and other adverse events.

- **34 participants** had serious adverse events.
- **None** of the participants died.

The researchers concluded there were no new or unexpected safety concerns for **ofatumumab** in this trial.

What serious adverse events did the participants have?

34 participants had serious adverse events. The table below shows the most common serious adverse events.

	Ofatumumab 562 participants
Bulging spinal disc Intervertebral disc protrusion	2 of 562 (less than 1%)
Non-cancerous growth in the uterus Uterine leiomyoma	2 of 562 (less than 1%)
Headache	2 of 562 (less than 1%)
Multiple sclerosis relapse	2 of 562 (less than 1%)
Thinking about suicide Suicidal ideation	2 of 562 (less than 1%)

What other (not including serious) adverse events did the participants have?

The table below shows the most common other adverse events.

	Ofatumumab 562 participants
Injection related reaction	300 of 562 (53%)
COVID-19	208 of 562 (37%)
Common cold Nasopharyngitis	96 of 562 (17%)
Headache	91 of 562 (16%)
Nose and throat infection Upper respiratory tract infection	78 of 562 (14%)

What was learned from this trial?

Researchers learned about the effects of **ofatumumab** in people with **relapsing multiple sclerosis (RMS)** who switched from other approved **RMS** treatments.

The researchers concluded that:

- Most participants had fewer than 1 relapse per year while receiving **ofatumumab**.
- There were no new or unexpected safety concerns for **ofatumumab** in this trial.

When this summary was written, Novartis had plans for future trials of **ofatumumab** in people with **RMS**.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is available on the Novartis Clinical Trial Results website **www.novctrd.com**

Follow these steps to find the scientific summary:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms **I accept** → Search for **COMB157G23101**

For more information about this trial, go to any of these websites:

clinicaltrials.gov – search using the number **NCT04353492**

euclinicaltrials.eu – search using the number **2023-507493-41-00**

Other trials of **ofatumumab** may appear on the public websites above. When there, search for **ofatumumab** or **OMB157**.

Full clinical trial title: A single-arm, prospective, multicentre, open-label study to evaluate ofatumumab treatment effectiveness and patient-reported outcomes (PRO) in patients with relapsing multiple sclerosis (RMS) transitioning from fumarate-based RMS approved therapies or fingolimod

NOVARTIS

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

1-888-669-6682 (US); +41-61-324 1111 (EU)

www.novartis.com/clinicaltrials