Clinical Study Results

Researchers look at the results of many studies to understand which medicines work and how they work. It takes a lot of people in many studies all around the world to advance medical science. This summary only shows the results from this one study. Other studies may find different results.

Thank you!

If you were part of this research study, Galderma, the sponsor of the study, would like to thank you for your participation.

Study name:
A study of the efficacy and safety of nemolizumab in adolescents and adults with atopic dermatitis (AD)

[A Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis]

Protocol number: RD.06.SPR.118161

Study sponsor:

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What is Atopic Dermatitis?

Atopic dermatitis (AD) is a long-term skin condition that is also known as eczema. When someone has AD, they may have itching, dryness, and sores on their skin. Sometimes these skin sores may be reddened, scaly, thickened, and/or oozing.

What is Nemolizumab?

Nemolizumab is a type of biological medicine called a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to a certain type of protein in the body. Nemolizumab belongs to a group of medicines called interleukin (IL) inhibitors. It blocks the binding of interleukin-31 (an immune system signaling molecule produced by the body that is involved in itch) to its receptor. By blocking this binding, nemolizumab is expected to break the itch-scratch cycle and allow the skin to heal.

Nemolizumab is administered by injections (shots) under the skin (into the tissue layer between the skin and the muscle). This type of injection is called a subcutaneous injection.

Where did the study take place?

The study took place at 161 centers in 14 countries: Australia, Austria, Canada, Czech Republic, Germany, Great Britain, Korea, Latvia, Lithuania, Netherlands, New Zealand, Poland, Spain, and the United States.

When was the study done?

The study started in August 2019 and ended in August 2022.

What was the main objective of the study?

In this study, researchers looked at nemolizumab compared to placebo (an injection that did not contain any medicine). The main goals were to check the efficacy (whether it worked well) and safety of nemolizumab.

Each person went through a screening process to made sure they met all requirements to become a participant in the study. Participants were then put into 2 groups by chance (randomized). Neither the doctors nor the participants knew who was given nemolizumab and who was given placebo (this is called double-blinded). This was done to make sure that the study results were not influenced in any way.

During the study, participants had visits with their study doctor for treatment with nemolizumab or placebo. At the visits, rating scales were used to assess how well the AD was responding to the treatment:

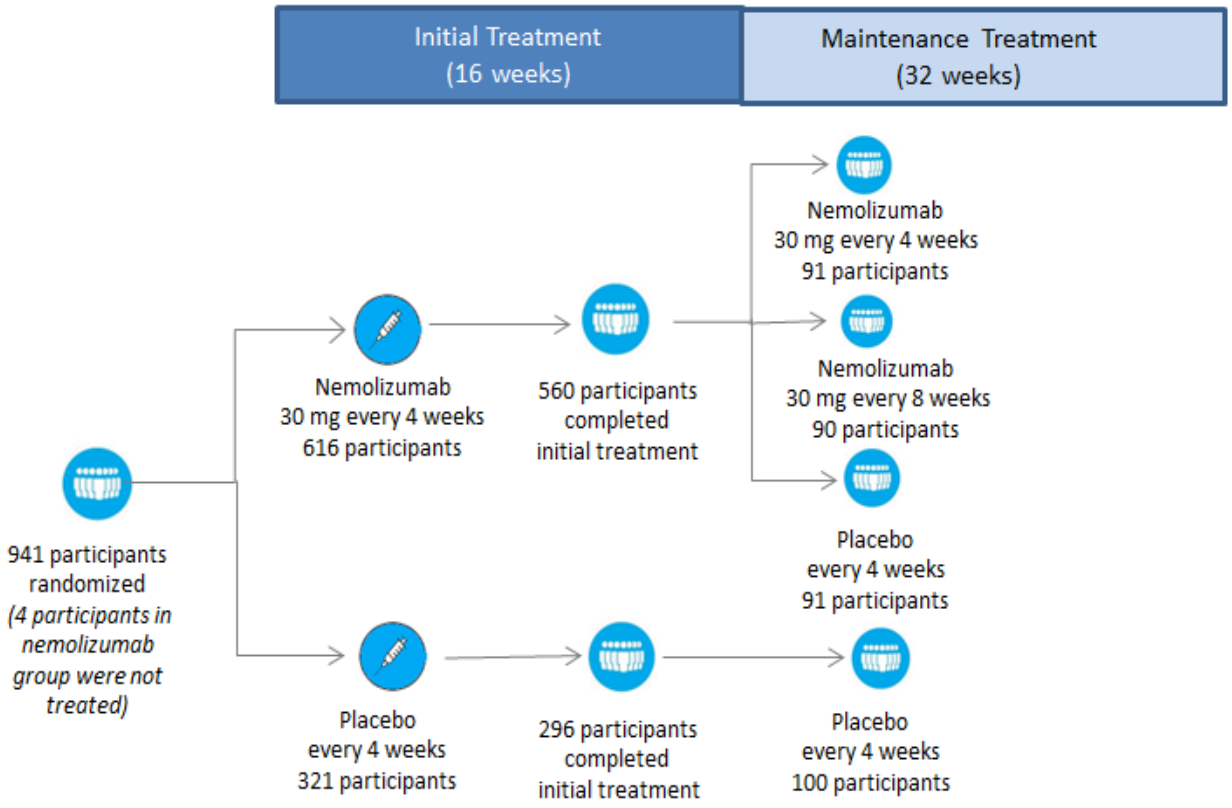
- Using the Investigator's Global Assessment (called the IGA for short), the study doctor or trained designee gave an IGA score from 0 to 4, where 4 means AD is more severe. The goal was to reach an IGA score of 0 or 1, meaning the AD skin sores were clear or almost clear, at the end of the initial treatment period.

- Using the Eczema Area and Severity Index (called the EASI for short), the study doctor or trained designee gave a rating from clear to very severe by looking at the area and intensity of AD involvement in each region of the body. The goal was to reach an EASI-75 which means 75% or more improvement from the start of the study to the end of the initial treatment period.

- Using the Peak Pruritus Numeric Rating Scale (called the PP NRS for short), participants reported the intensity of their pruritus (itch) on a scale of 0 to 10, where 0 is "no itch" and 10 is the "worst itch imaginable". Based on previous studies, a four-point reduction of the weekly average PP NRS score was considered a meaningful improvement for the participants.

- Using other scales and assessments, the study doctors collected information on how well nemolizumab worked.

At the end of the initial treatment period, participants who received nemolizumab who had an IGA score of 0 or 1 *or* an EASI-75 were put into 3 groups by chance (randomized) for the maintenance treatment period. Participants who responded to placebo in the initial treatment period continued to receive placebo in the maintenance treatment period.



Participants who did not reach the treatment goal during the initial treatment period were given the chance to enter a long-term treatment study with nemolizumab. You can learn more about this other study in the section below called “Are there plans for more studies?”.

The study doctors also looked at whether nemolizumab was safe to use in the treatment of AD. They did this by asking the participants to report all unwanted or unexpected effects of the medicine during the study and to undergo physical exams, respiratory (lung) tests, laboratory tests (both blood and urine), and ECGs. ECG stands for electrocardiogram which is a graph showing the heart’s electrical activity.

Who was included in the study?

- 441 females participated
- 500 males participated
- participants were between the ages of 12 and 82 years
- the average age of the participants was 33 years

Participants in this study had to:

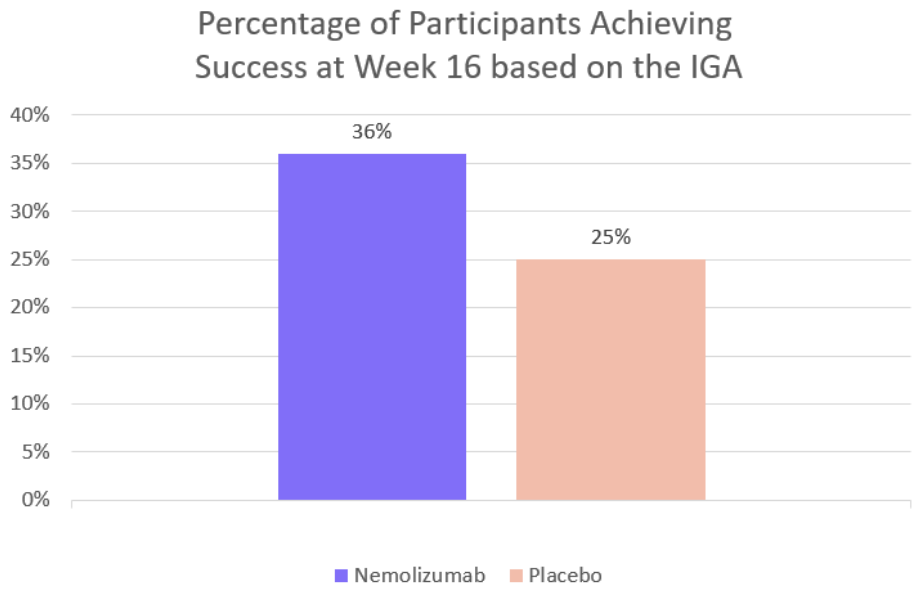
- be at least 12 years old
- have a diagnosis of AD for at least 2 years
- have moderate to severe AD
- have tried topical medicine (meaning medicine applied directly to the skin) for their AD and found that it did not work well enough
- agree to use birth control (for female participants able to get pregnant)

A potential participant could not take part in the study if they:

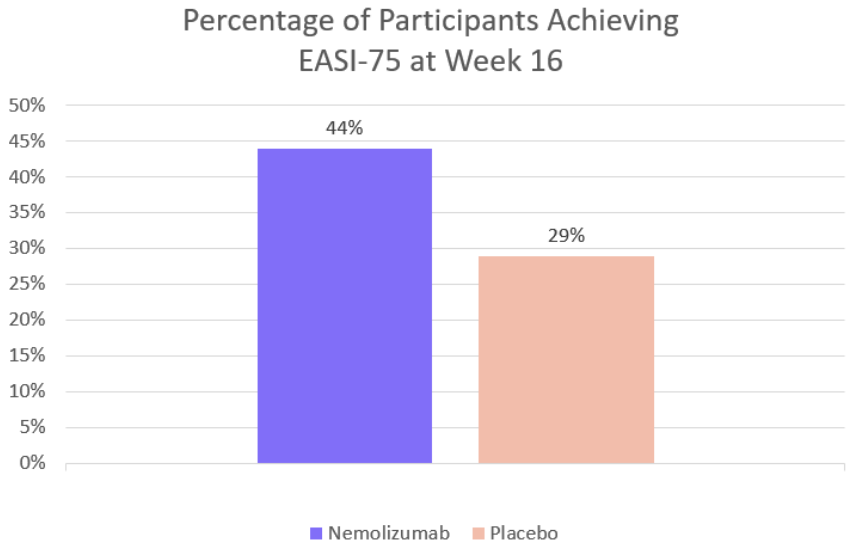
- weighed less than 30 kg (this is about 66 pounds)
- were recently in the hospital for asthma treatment
- had asthma that was not well-controlled
- could not use topical medicine for their AD due to allergies or another medical reason
- had other recent or current conditions such as chronic obstructive pulmonary disease (a lung condition that causes breathing difficulties), chronic bronchitis (long-term inflammation of the breathing tubes), tuberculosis (TB), certain types of cancer, or certain infections
- had another condition that would make it too risky for them to participate
- had immunosuppression (the immune system is not functioning as well as it should)
- had an allergy to any part of the study treatment
- were pregnant

What were the overall results of the study?

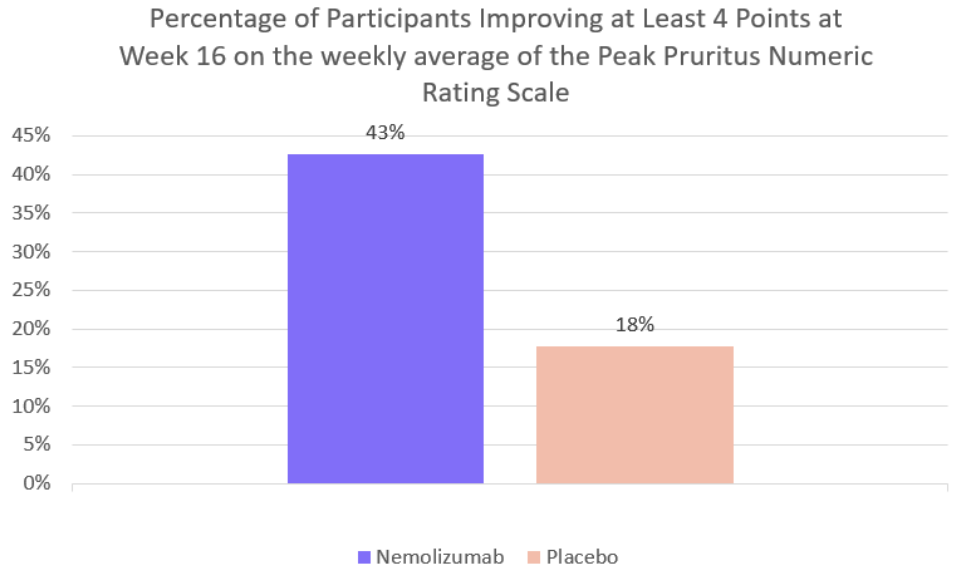
Nemolizumab was able to improve the AD skin sores. The chart below shows the percentage of participants who had an IGA score of 0 or 1 at week 16 *and* had their IGA score decrease by at least 2 points from the start of the study.



Nemolizumab was able to improve the area and intensity of the AD. The chart below shows the percentage of participants who reached the goal of 75% or more improvement on the EASI from the start of the study to the end of the initial treatment period (which was week 16).



Nemolizumab was able to improve the itch. The chart below shows the percentage of participants who reached the goal of at least a 4-point improvement of their weekly average PP NRS scores from the start of the study to week 16.



Study results also showed:

- Nemolizumab was able to improve quality of life and sleep quality.
- Participants taking nemolizumab who achieved the study goals in the initial treatment period kept those results during the maintenance treatment period.

What were the unwanted or unexpected effects of the medicine reported in the study?

In the initial treatment period, 306 participants out of 616 (about 50%) who received nemolizumab and 146 participants out of 321 (about 46%) who received placebo had at least 1 unwanted or unexpected effect of the medicine. Of these, 123 participants out of 616 (20%) who received nemolizumab and 42 participants out of 321 (13%) who received placebo had at least 1 unwanted or unexpected effect of the medicine that were believed to be caused by the study treatment.

Commonly reported unwanted or unexpected effects of the medicine in the initial treatment period that were believed to be caused by the study treatment

Unwanted or unexpected effects of the medicine experienced by at least 1% of participants in either group during the initial treatment period	No. of participants in the nemolizumab group who experienced this unwanted or unexpected effect of the medicine	No. of participants in the placebo group who experienced this unwanted or unexpected effect of the medicine
Atopic dermatitis (a type of eczema)	23 out of 616 participants (4%)	7 out of 321 participants (2%)
Asthma (a lung disease in which there is a tightening of air passages leading to wheezing and shortness of breath)	15 out of 616 participants (2%)	8 out of 321 participants (3%)
Headache	10 out of 616 participants (2%)	3 out of 321 participants (1%)
Nausea	6 out of 616 participants (1%)	0 out of 321 participants (0%)

The following participants had at least 1 unwanted or unexpected effect of the medicine during the maintenance treatment period:

- 53 participants out of 91 (58%) who received nemolizumab every 4 weeks in the initial treatment period and the maintenance treatment period
- 50 participants out of 90 (56%) who received nemolizumab every 4 weeks in the initial treatment period and every 8 weeks in the maintenance treatment period
- 53 participants out of 91 (58%) who received nemolizumab every 4 weeks in the initial treatment period and placebo in the maintenance treatment period
- 55 participants out of 100 (55%) who received placebo in the initial treatment period and the maintenance treatment period

The following participants had at least 1 unwanted or unexpected effect of the medicine that were believed to be caused by the study treatment during the maintenance treatment period.

- 10 participants out of 91 (11%) who received nemolizumab every 4 weeks in the initial treatment period and the maintenance treatment period
- 15 participants out of 90 (17%) who received nemolizumab every 4 weeks in the initial treatment period and every 8 weeks in the maintenance treatment period
- 9 participants out of 91 (10%) who received nemolizumab every 4 weeks in the initial treatment period and placebo in the maintenance treatment period
- 11 participants out of 100 (11%) who received placebo in the initial treatment period and the maintenance treatment period

Commonly reported (at least 2 participants in any group) unwanted or unexpected effects of the medicine in the maintenance treatment period that were believed to be caused by the study treatment

Unwanted or unexpected effects of the medicine experienced by at least 2 participants in any group during the maintenance treatment period	No. of participants in nemolizumab every 4 weeks (initial) to every 4 weeks (maintenance) group who experienced this unwanted or unexpected effect of the medicine	No. of participants in nemolizumab every 4 weeks (initial) to every 8 weeks (maintenance) group who experienced this unwanted or unexpected effect of the medicine	No. of participants in nemolizumab (initial) to placebo (maintenance) group who experienced this unwanted or unexpected effect of the medicine	No. of participants in placebo (initial) to placebo (maintenance) group who experienced this unwanted or unexpected effect of the medicine
Atopic dermatitis (a type of eczema)	2 out of 91 participants (2%)	2 out of 90 participants (2%)	2 out of 91 participants (2%)	2 out of 100 participants (2%)
Asthma (a lung disease in which there is a tightening of air passages leading to wheezing and shortness of breath)	3 out of 91 participants (3%)	2 out of 90 participants (2%)	1 out of 91 participants (1%)	2 out of 100 participants (2%)
Acne	0 out of 91 participants (0%)	2 out of 90 participants (2%)	1 out of 91 participants (1%)	0 out of 100 participants (0%)
Herpes dermatitis	0 out of 91 participants (0%)	2 out of 90 participants (2%)	1 out of 91 participants (1%)	0 out of 100 participants (0%)

Most of the unwanted or unexpected effects of the medicine in participants that received nemolizumab during either treatment period (initial or maintenance) were mild or moderate in severity and the majority resolved by the end of the study.

There were no deaths during the research study.

An unwanted or unexpected effect of the medicine is considered serious when it is life-threatening, requires treatment in the hospital, or causes long-lasting effects.

- During the initial treatment period, 6 participants out of 616 (1%) who received nemolizumab and 4 participants out of 321 (1%) who received placebo had at least 1 serious unwanted or unexpected effect of the medicine. None of the events were believed to be caused by the study treatment.

- During the maintenance treatment period, the following participants had at least 1 serious unwanted or unexpected effect of the medicine. None of the events were believed to be caused by the study treatment.

    - 4 participants out of 91 (4%) who received nemolizumab every 4 weeks in the initial treatment period and the maintenance treatment period
    - 3 participants out of 90 (3%) who received nemolizumab every 4 weeks in the initial treatment period and every 8 weeks in the maintenance treatment period
    - 2 participants out of 91 (2%) who received nemolizumab every 4 weeks in the initial treatment period and placebo in the maintenance treatment period
    - 1 participant out of 100 (1%) who received placebo in the initial treatment period and the maintenance treatment period

Some participants stopped getting the study treatment due to unwanted or unexpected effects of the medicine.

- During the initial treatment period, 11 participants out of 616 (2%) who received nemolizumab and 13 participants out of 321 (4%) who received placebo stopped getting the study treatment due to unwanted or unexpected effects of the medicine.

- During the maintenance treatment period, the following participants stopped getting the study treatment due to unwanted or unexpected effects of the medicine.

    - 1 participant out of 91 (1%) who received nemolizumab every 4 weeks in the initial treatment period and the maintenance treatment period
    - 3 participants out of 90 (3%) who received nemolizumab every 4 weeks in the initial treatment period and every 8 weeks in the maintenance treatment period
    - 2 participants out of 91 (2%) who received nemolizumab every 4 weeks in the initial treatment period and placebo in the maintenance treatment period
    - 2 participants out of 100 (2%) who received placebo in the initial treatment period and the maintenance treatment period

During the whole study, the study doctors did not find any concerns with the participants' physical exam results, respiratory (lung) test results, laboratory test results (either blood or urine), or with their ECG results.

Are there plans for more studies?

There is an ongoing study called RD.06.SPR.118163 at centers in Europe, the Americas, and Asia-Pacific which aims to learn how safe and how well nemolizumab works over a longer period of use (up to 4 years).

Where can I learn more about this study?

A description of this study and a summary of results will be available on the following websites.

- www.clinicaltrialsregister.eu using the study identifier 2019-001887-31
- www.ClinicalTrials.gov using the study identifier NCT03985943

These web sites can be searched any time and do not include information that can identify a participant.