Clinical Study Results

1. Study Name

Title of the Study:	A Phase 3b, Open-label, Single-arm Study of the Efficacy and Safety of Apremilast, in Subjects with Plaque Psoriasis that is not Adequately Controlled by Topical Therapy
Brief Title:	A Study of the Efficacy and Safety of Apremilast, in Subjects With Plaque Psoriasis That is Not Adequately Controlled by Topical Therapy
Protocol Number:	CC-10004-PSOR-023 (20200062)
EU Trial Number:	Not applicable
Other Identifiers:	NCT03930186
Date of This Summary:	7 May 2021

What does this summary cover?

This summary shows the main results from one clinical study. The results are only for this study. Other studies may find different results. Researchers and health authorities look at the results of many studies to decide which medicines work best and are safest for participants.

Amgen has committed to make research results available to the public. This summary has been provided as part of that commitment and should not be used for any other purpose. It should not be considered to make a claim for any product or to guide treatment decisions.

Some information in this summary may be different from the approved labelling for apremilast. Your healthcare professional should refer to the full prescribing information for proper use of apremilast.

2. Who Sponsored This Study?

Amgen Inc.
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Amgen Inc. is the sponsor of the study and makes apremilast, the medicine tested in the study. Amgen would like to thank everyone who participated in this study and feels it is important to share the results of this study.

3. General Information About the Clinical Trial

Where and when was the study done?

- This study took place in Japan.
- The study began in May 2019 and ended in September 2020.
- The study was completed as planned.

Why was the study done?

Plaque psoriasis is an autoimmune skin condition that causes “plaques”, raised red patches covered with dead skin cells that appear white. These plaques can be itchy and painful. Plaque psoriasis occurs when the immune system mistakes normal cells in the body as unwanted invaders and attacks these cells. Depending on how bad the condition is, or how many and how big the plaques a person has, this condition can be mild, moderate, or severe. Participants in this study had mild to moderate plaque psoriasis as determined by their doctor.

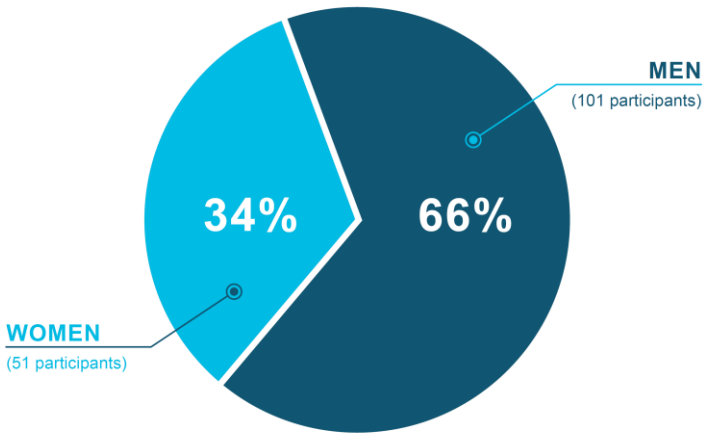
Apremilast works by blocking an enzyme in the body called phosphodiesterase 4 (PDE4) that is usually increased in medical conditions involving inflammation, such as the reddening and itching of the skin in psoriasis. Apremilast is available in the form of tablets and is taken by mouth. Apremilast has been approved for the treatment of moderate to severe plaque psoriasis.

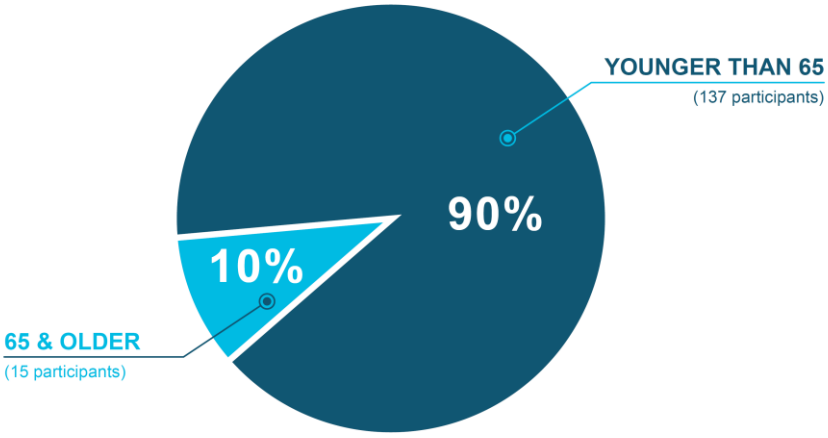
This was a phase 3 study, the late stage of the development process of medicines for humans. The main purpose of this study was to find out if participants with mild to moderate plaque psoriasis who took apremilast plus topical therapy (medicines applied to the skin) would achieve clear or almost clear skin after 16 weeks of treatment.

4. Who Was Included in This Study?

Who took part in the study?

This study included 152 participants with mild to moderate plaque psoriasis. 51 participants (34%, or about 34 out of 100) were women and 101 participants (66%, or about 66 out of 100) were men. They ranged in age from 20 to 82 years. 137 participants (90%, or about 90 out of 100) were younger than 65 years old and 15 participants (10%, or about 10 out of 100) were at least 65 years old or older.





This study took place at 28 study centers in Japan.

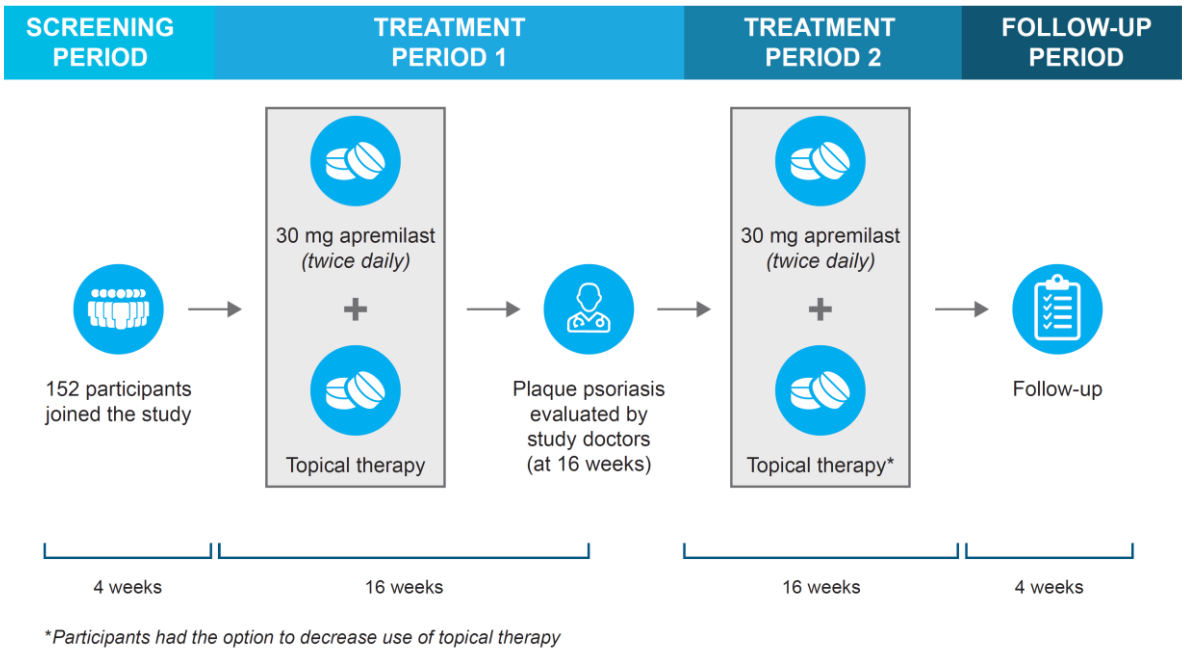
Participants were examined by a study doctor and chosen to be in the study if they met certain study requirements:

- were 20 years of age or older;
- were diagnosed with chronic plaque psoriasis for at least 6 months before starting the study;
- had mild to moderate plaque psoriasis as measured by the study doctor;
- were in general good health other than plaque psoriasis;
- had been treating their plaque psoriasis with topical therapy only for at least 4 weeks before starting the study;
- had not had adequate improvement treating their plaque psoriasis with topical therapy only

5. Which Medicines Were Studied?

Apremilast is the medicine evaluated in this study. Participants began with a dose of 10 mg apremilast, which was slowly increased over the first week of treatment, until the full dose of 30 mg apremilast twice a day was reached. Participants continued taking this dose (30 mg apremilast twice a day) until the end of the study treatment period.

This study had 4 parts: a 4-week screening period, a 16-week treatment period during which participants used both apremilast and their topical therapy, a second 16-week treatment period during which participants continued taking apremilast but were able to stop their topical therapy, and a 4-week follow-up period. This was an open-label study, which means that both the participants and the study doctors knew what medicines the participants received.



6. What Were the Side Effects?

What is a side effect?

All medicines can cause side effects, or unwanted medical problems that may happen when you take a medicine. In this study, doctors reported all the medical problems participants had. Doctors believed some of the problems could have been caused by the study treatment(s). These possible side effects are listed below.

What side effects were seen?

The tables below show how many participants had side effects that could have been caused by the study medicine(s).

Side Effects During the Study

	30 mg Apremilast Twice Daily (152 Participants)
How many participants had serious side effects?	1 participant (1%)
How many participants had non-serious side effects?	88 participants (58%)
How many participants died from side effects?	0 participants (0%)
How many participants stopped taking the study medicine because of side effects?	4 participants (3%)

If a participant had to stay in the hospital or died because of a side effect, the doctor reported that the side effect was serious. No participant died due to a side effect.

The table below shows the serious side effects.

Serious Side Effects During the Study	
Serious Side Effect	**30 mg Apremilast Twice Daily (152 Participants)**
Creatine phosphokinase increased (an enzyme found in the brain, heart, and skeleton muscles)	1 participant (1%)
Stomach flu	1 participant (1%)

*Both of the serious side effects happened in the same participant.

The table below shows the non-serious side effects that occurred in at least 5% of participants (or about 1 out of 20).

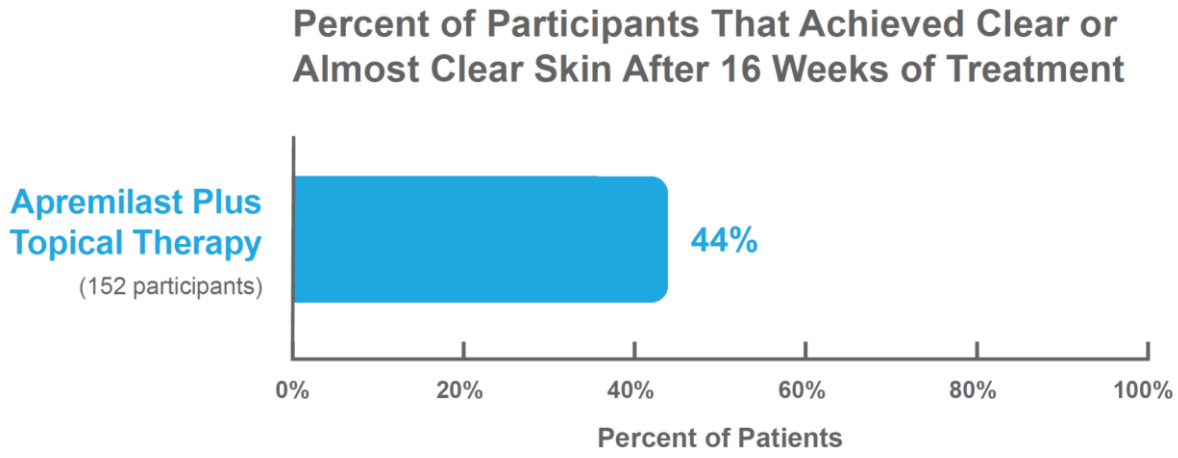
Non-serious Side Effects During the Study	
Non-serious side effect	**30 mg Apremilast Twice Daily (152 Participants)**
Diarrhea	29 participants (19%)
Nausea	28 participants (18%)
Soft stool	20 participants (13%)
Headache	19 participants (13%)

This section only shows the most often reported side effects considered by the study doctor as related to a study medicine. No single clinical study can give a complete picture of the benefits and risks of a medicine. Information about other side effects may be available at the website listed at the end of this summary.

7. What Were the Overall Results of the Study?

Did participants who took apremilast plus topical therapy achieve clear or almost clear skin after 16 weeks of treatment?

- To answer this question, the researchers measured the improvement of plaque psoriasis using the static Physician Global Assessment (sPGA) score to find out how many participants had ‘clear skin’ (ie, no plaques) or ‘almost clear skin’ (score of 0 or 1) after the first 16-week treatment period.
- In this study, 44% of participants achieved clear or almost clear skin after 16 weeks of treatment with apremilast plus topical therapy.
- These results are based on information that was collected until the researchers had finished gathering the information needed to achieve the main aim of the study.
- This study was completed as planned.
- More results may be available at the website listed at the end of this summary.



8. How Has This Study Helped Participants and Researchers?

What else is important to know about these results?

These results are only for this clinical study, which looked at a sample of 152 people with mild to moderate plaque psoriasis. Not all participants in the study had the same results. The results for any single participant could have been better or worse than the results for their group. Other studies may find different results. These results do not explain how a medicine may work in a single person. Many studies are needed to show the benefits and risks of a medicine that is still being tested.

This research may help future participants and families by helping doctors understand more about the treatment being studied.

9. Are There Plans for Further Studies?

If more clinical studies are done, they may be listed on public websites, such as those below. Search for apremilast (Otezla®) on the websites below.

10. Where Can I Find More Information About This Study?

To find out more about this study, check this website:

- www.clinicaltrials.gov. Use the study identifier NCT03930186

If you participated in the study and have questions about the study results, the doctor or staff at your study site may be able to answer them.