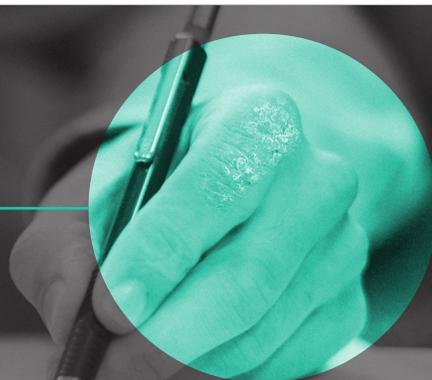


Summary of Clinical Trial Results

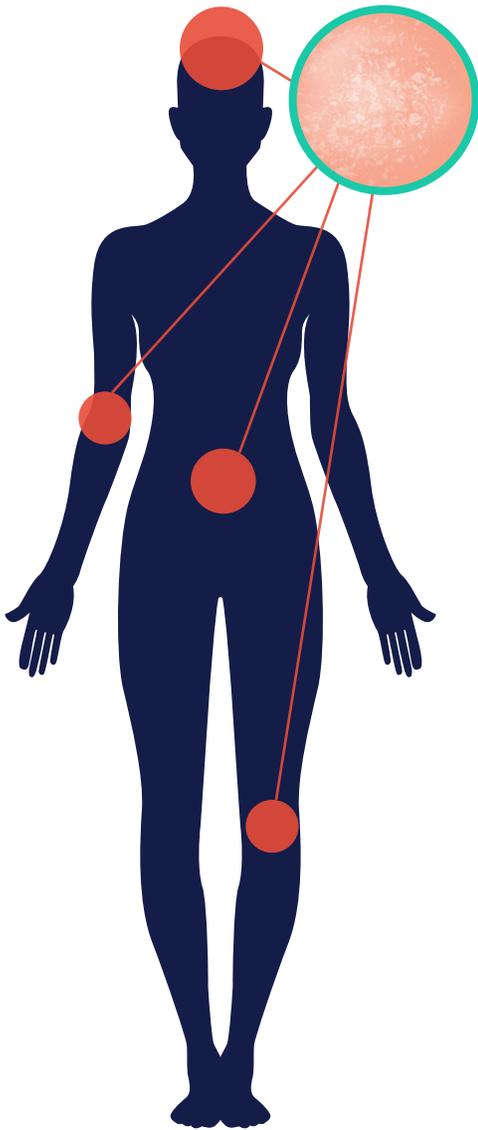
For Laypersons

A study to learn how effective and safe a medicine containing the study drug risankizumab works compared to the study drug FUMADERM® (already approved treatment) to treat adult patients with moderate to severe plaque psoriasis



Overall Summary

- Psoriasis is a skin disorder which causes the skin cells to multiply faster (almost 10 times more) than normal, making the skin look uneven.
- The skin of psoriasis patients can become patchy, red, itchy, and covered with white scales.
- There are many types of psoriasis, but plaque psoriasis is the most common.
- The reason people have psoriasis is unknown, though researchers think it is linked with the body's immune system.
- Study doctors aimed to test a medicine called risankizumab, which affects the immune system, to treat symptoms of psoriasis.
- The study took place in Germany from August 2017 to July 2018.
- In this study, study doctors compared the effects and safety of risankizumab with FUMADERM® in patients with moderate to severe plaque psoriasis.
- A total of 120 adult patients took part in the study. The study doctors put the patients into two groups. One group received risankizumab injection and the other received FUMADERM® tablets.
- This study showed benefits of taking risankizumab in treating moderate to severe plaque psoriasis.
- The number of side effects was similar to what was expected in patients with moderate to severe plaque psoriasis.
- The results of this study may be used by researchers to further develop this medicine. If you participated in this study and wish to see your results, contact the doctor or staff at your study site.



1. General information about the study

1.1 Why did we perform this study?

Researchers are looking for a better way to treat a skin disease called psoriasis. Skin cells multiply much faster than normal cells in people with psoriasis. This makes the skin grow rough red patches covered with white scales. The patches can heal and come back again. These patches are mostly found on the scalp, elbows, knees, and lower back. There are many types of psoriasis, but plaque psoriasis is the most common, affecting 2% of the world population. The exact cause of psoriasis is unknown. Researchers think that when the body's immune system is disturbed, skin cells can multiply faster. This results in new cells multiplying too fast and can lead to psoriasis in some people.

There is no cure for psoriasis, but treatment relieves the symptoms. Researchers are looking for a treatment that prevents rapid cell multiplication caused by psoriasis by weakening the activity of the immune system. Many drugs with this ability have been tested in other studies. In this study, a new drug called risankizumab was tested for benefits and safety in psoriatic patients compared to FUMADERM®, another psoriasis treatment.

Researchers planned this study as a Phase 3 open-label study. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. This study was “open-label with blinded assessment”, which means that both patients and study doctors knew which treatments were given, but the assessor did not know. This ensures that no study results were influenced.

The study doctors looked at the benefits of risankizumab versus FUMADERM® in patients after 24 weeks of treatment. FUMADERM® is a medication used in the treatment of plaque psoriasis. The study doctors also reported any side effects patients may have had after treatment with risankizumab or FUMADERM®.

The main aim of the study was to find out if patients had fewer signs of plaque psoriasis after taking risankizumab, and if there were any unwanted side effects. This summary only includes the results from this study, which may be different from the results of other studies.

1.2 When and where was this study done?

This study took place from August 2017 to July 2018 in Germany.



2. What patients were included in this study?



A total of 120 adult patients took part in the study. Among the 120 patients, 107 completed the study and 13 did not. All of the patients who did not complete the study were a part of the patient group treated with FUMADERM®: 3 patients left the study due to side effects, 2 patients were lost to follow-up (patient[s] did not return to continue treatment or testing), 2 patients left the study by their own choice, and 6 patients left the study for other reasons. All patients had moderate or severe plaque psoriasis for at least 6 months. Each patient was a candidate to receive oral or injectable treatment for psoriasis, but had previously received only topical treatment (treatment applied to the skin).

There were more men (59.2%) than women (40.8%) in the study. Study doctors selected only adults to participate in this study. Patients ranged from 18 to 73 years of age.



3. Which medicines were studied?

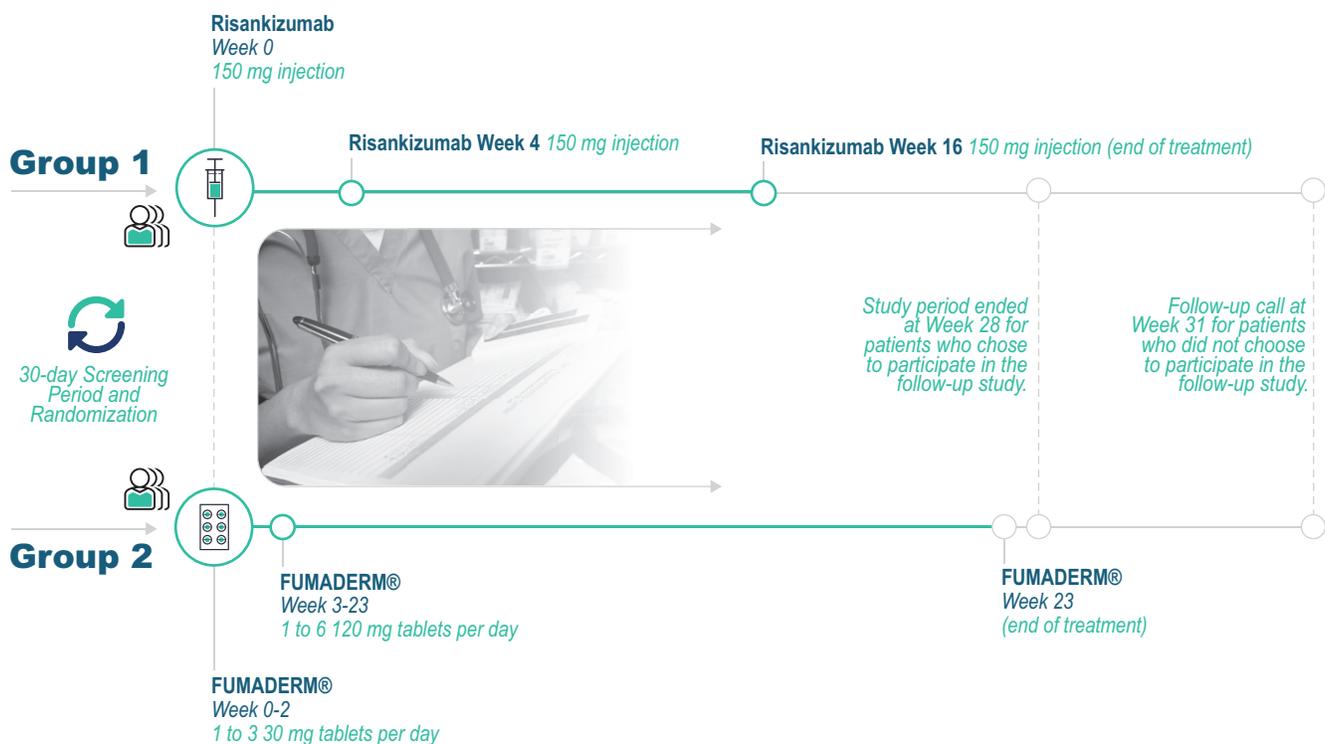
The medicine in this study was called risankizumab, which was compared with another medicine, FUMADERM®, a treatment used to treat plaque psoriasis for many years. There were 2 groups in this study. One group was given risankizumab via injection under the skin and the other group was given FUMADERM® via tablets taken orally.

The study was divided into a 30-day screening period, a 24-week treatment period, and a follow-up call at Week 31 for patients who did not choose to participate in the separate follow-up study. The study period ended at Week 28 for patients who chose to participate in the follow-up study.

Before the study started, a screening period of 30 days took place to check if patients could join the study. Study doctors tested patients with several different types of physical examinations in order to see if they could participate in the study.

At the beginning of the study, the study doctors randomly (by chance) put the patients into 1 of the 2 groups. The study doctors made sure that each group had a similar number of patients who had moderate to severe plaque psoriasis. This process is called “randomization”, which helps make the groups equal and reduces the differences between the groups. Study doctors gave the patients risankizumab or FUMADERM® depending on which group they were in. Patients in one group received a risankizumab 150 milligram (mg) injection under the skin at Weeks 0, 4, and 16. Patients in the other group received 1 to 3 tablets of FUMADERM® 30 mg each day from Week 0 to Week 2, and then 1 to 6 tablets of 120 mg FUMADERM® each day from Week 3 to Week 23, depending on the patient’s response to treatment. The patients knew which medicine they were taking.

The diagram below displays how different treatments were given to patients in different groups:



4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time. Related side effects are side effects that were at least possibly related to the study drug.

About 3.5% of patients receiving FUMADERM® (2 patients) had serious side effects; of these, none were related to study drug. About 1.7% of patients receiving risankizumab (1 patient) had serious side effects; this patient had side effects considered related to risankizumab (influenza [flu] and chronic obstructive pulmonary disease [COPD]).

About 8.8% of patients receiving FUMADERM® (5 patients) stopped taking the study drug because of side effects; all of these side effects were considered related to study drug. No patient receiving risankizumab stopped taking the study drug because of side effects. No patients died during the study.

The table below shows information about the related serious side effects patients had in the study, as well as related side effects patients had that led to the patient stopping the study drug, and related side effects leading to death.

	FUMADERM® N=57 patients	RISANKIZUMAB N=60 Patients
Number of patients with related serious side effects	0 (0% of patients)	1 (1.7% of patients)
Number of patients who stopped taking part because of side effects	5 (8.8% of patients)	0 (0% of patients)
Number of patients with related side effects leading to death	0 (0% of patients)	0 (0% of patients)

All patients receiving FUMADERM® had side effects during the study (57 patients). About 91.2% of these patients (52 patients) had a side effect considered related to study drug.

About 81.7% of patients receiving risankizumab (49 patients) had side effects during the study; of these, 25.0% of patients (15 patients) had a side effect considered related to study drug.

The table below shows information about related side effects in this study. The most common related side effects were diarrhea, upper abdominal pain, and flushing. More side effects were seen in the FUMADERM® group than risankizumab group.

	FUMADERM® N=57 patients	RISANKIZUMAB N=60 Patients
Number of patients with at least one related side effect	52 (91.2% of patients)	15 (25.0% of patients)
Diarrhea	32 (56.1% of patients)	0 (0% of patients)
Abdominal pain upper	26 (45.6% of patients)	1 (1.7% of patients)
Flushing	23 (40.4% of patients)	0 (0% of patients)
Abdominal pain	10 (17.5% of patients)	0 (0% of patients)
Nausea	9 (15.8% of patients)	0 (0% of patients)
Lymphopenia (low white blood cell count)	8 (14.0% of patients)	0 (0% of patients)
Nasopharyngitis (cold)	5 (8.8% of patients)	7 (11.7% of patients)
Dizziness	4 (7.0% of patients)	0 (0% of patients)

5. What were the overall results of the study?

The study was completed as planned. Researchers throughout this study aimed to determine the safety and effectiveness of risankizumab compared to FUMADERM®.

To find out the main results of the study, doctors assessed whether patients receiving risankizumab or FUMADERM® were able to achieve a 90% reduction in the Psoriasis Area Severity Index score (PASI90), which measures improvement in symptoms of psoriasis. The study doctors found that the patients in the study groups who received risankizumab had fewer signs of plaque psoriasis at Week 24 compared to patients who had taken FUMADERM®. About 83.3% of patients who received risankizumab achieved a 90% or more reduction in their symptoms of plaque psoriasis. Whereas about 10.0% of patients who received FUMADERM® showed a 90% or more reduction in their symptoms of plaque psoriasis. The number and frequency of side effects were similar to those expected in patients with moderate to severe plaque psoriasis.

6. How has the study helped patients and researchers?

These results helped the researchers learn the safety and benefits of risankizumab compared with FUMADERM® in the treatment of plaque psoriasis. Findings from this study may be used in other studies to learn whether patients are helped by risankizumab.

This summary only shows the results of this study, which may be different from the results of other studies. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

7. Are there any plans for future studies?

There are plans for future studies of risankizumab in this patient population.

8. Who sponsored this study?

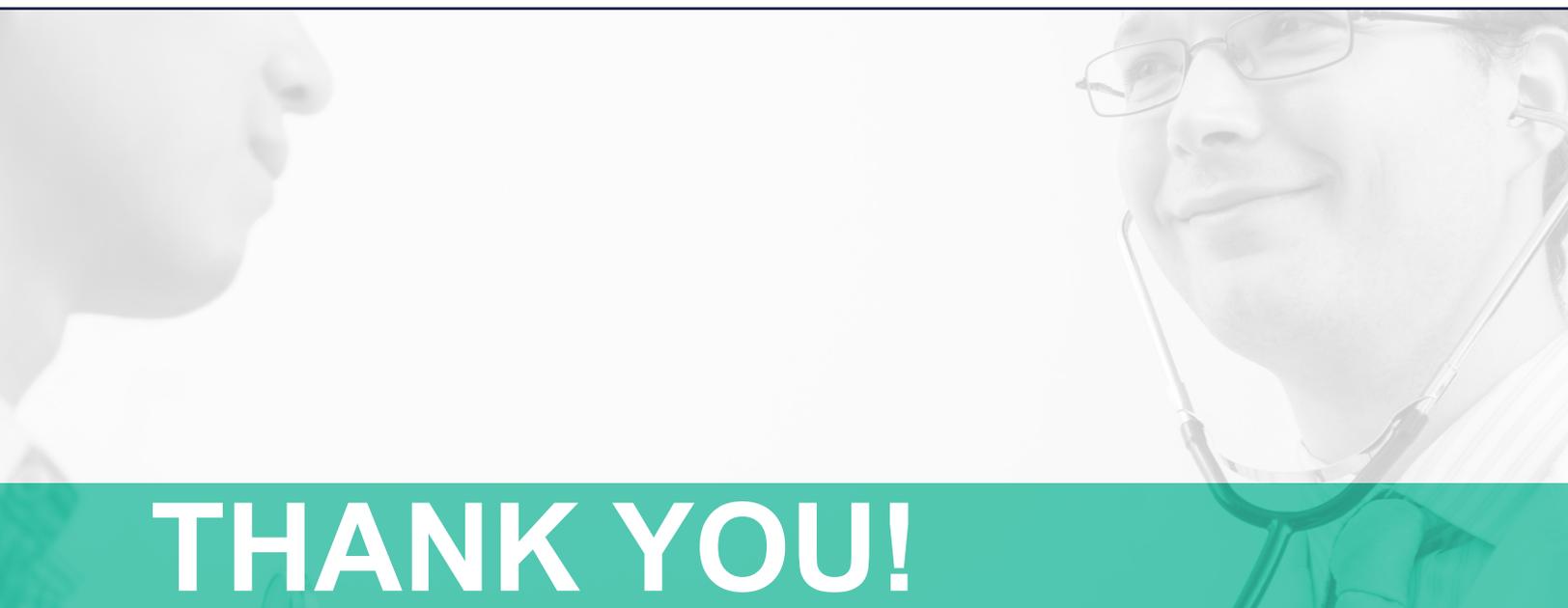
This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.



9. Where can I find out more information about this study?

Title of Study	A Randomized, Controlled, Multicenter, Open Label Study with Blinded Assessment of the Efficacy of the Humanized Anti-IL 23p19 Risankizumab Compared to FUMADERM® in Subjects with Moderate to Severe Plaque Psoriasis Who are Naïve to and Candidates for Systemic Therapy
Protocol Number	M16-178
ClinicalTrials.gov	NCT03255382 https://clinicaltrials.gov/ct2/show/NCT03255382
EudraCT	2016-003718-28 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003718-28
Study Sponsor	AbbVie Inc Phone: (800) 633-9110 Email: abbvieclinicaltrials@abbvie.com

25July2019. This document includes known facts as of the time the document was finalized.



THANK YOU!

Abbvie wants to thank all the participants for their time and effort that went into making this study possible.

**Clinical study
participants help
advance science!**