

# Summary of Clinical Trial Results

For Laypersons



**A study to learn how effective and safe a new formulation of risankizumab is compared to placebo (no medicine) for patients with moderate to severe plaque psoriasis**

## Overall Summary

- Psoriasis is a long-term skin disease which causes red, itchy scaly patches most commonly on the knees, elbows, scalp, and torso (chest, back, abdomen).
- There are many types of psoriasis, but plaque psoriasis is the most common.
- The reason people have psoriasis is unknown, but researchers think it may be linked to the immune system, which works to protect the body from infection.
- This study took place from May 2019 to July 2020 in the United States.
- Study doctors compared the safety and efficacy (how well treatment worked) of a new formulation of risankizumab to placebo (looks like medicine but contains no active drug).
- The new formulation uses a single pre-filled syringe (PFS) injection at each dose.
- A total of 157 adult patients took part in the study and 124 completed the study. Patients were placed into 2 groups by a computer program. One group was given risankizumab and the other was given placebo.
- The main goals of the study were to see if patients' symptoms of psoriasis improved after 16 weeks of treatment based on the Psoriasis Area and Severity Index (PASI), which measures psoriasis areas (lesions) and their redness, thickness, and scaliness and the static Physician's Global Assessment (sPGA), which also measures the severity of skin lesions.
- Patients who took risankizumab had greater improvements in their PASI and sPGA scores than patients who took placebo.
- 5.7% of patients (6 patients) given risankizumab and 3.8% of patients (2 patients) given placebo had side effects. The most common side effects were nausea and nasal congestion.
- The results of this study may be used by researchers to further develop this medicine.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

# 1. General information about the study

## 1.1. What was the main objective of 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 develop rough red patches with white scales. The patches can heal and come back again and are most often found on the knees, elbows, scalp, and torso (chest, back, abdomen). Symptoms are different for every patient.

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, but researchers think it may be caused by the body's immune system.

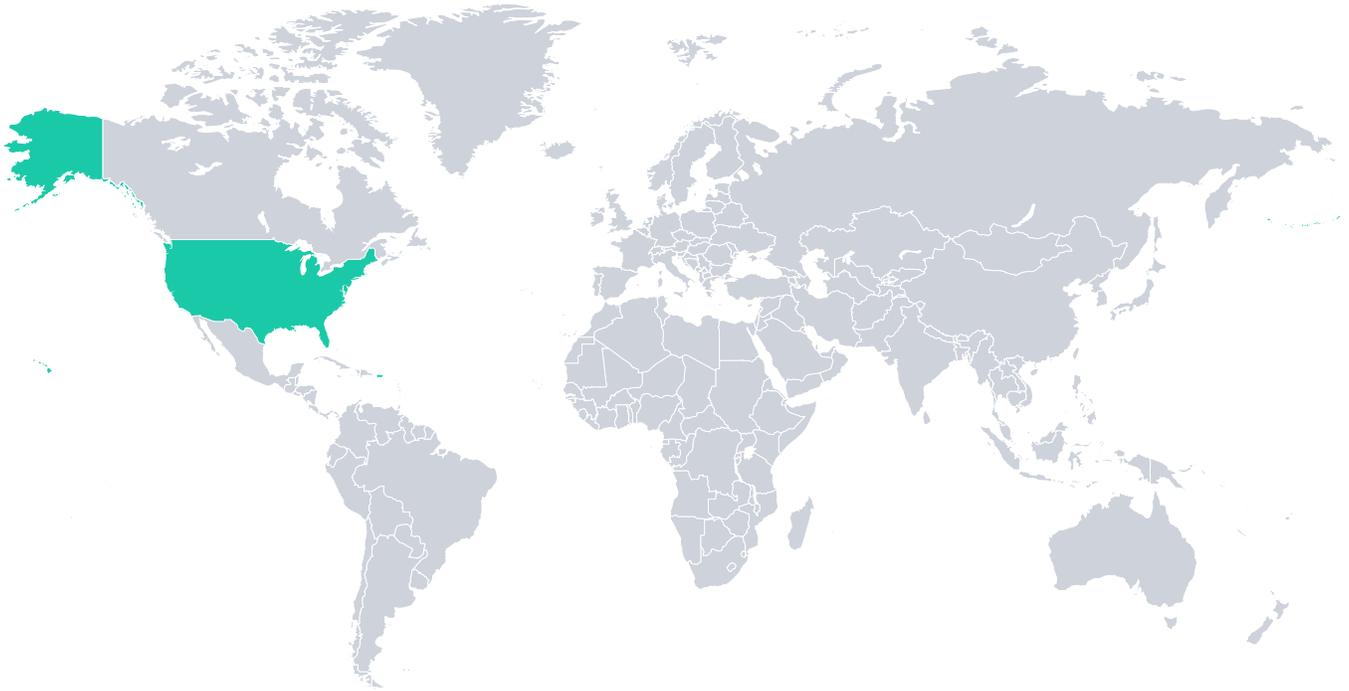
There is no cure for psoriasis, but researchers are looking for a treatment that weakens the activity of the immune system to relieve patients' symptoms. In this study, the benefits and safety of a drug called risankizumab was tested compared to placebo in patients with psoriasis. This study was a Phase 3, "double-blind" study.

- **Phase 3** studies test potential new treatments in a large number of patients with a disease.
- This study was **double-blind**, which means that neither the patients nor the study doctors knew who was given which treatment. This helps to ensure that study results were not influenced.
- A computer program was used to randomly (by chance) put patients into 1 of 2 groups. This process is called **randomization**, which helps make the groups similar and reduces differences between groups. Randomization allows the results of each treatment to be compared as accurately as possible.
- The study also looked for any **side effects** after starting treatment. Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to treatment.

The main goal of the study was to find out whether treatment with a new formulation of risankizumab in a pre-filled syringe (PFS) improved psoriasis symptoms when compared to treatment with placebo in a PFS. The new formulation of risankizumab uses a single injection at each dose.

## 1.2. When and where was the study done?

This study took place from May 2019 to July 2020 in the United States (including Puerto Rico).

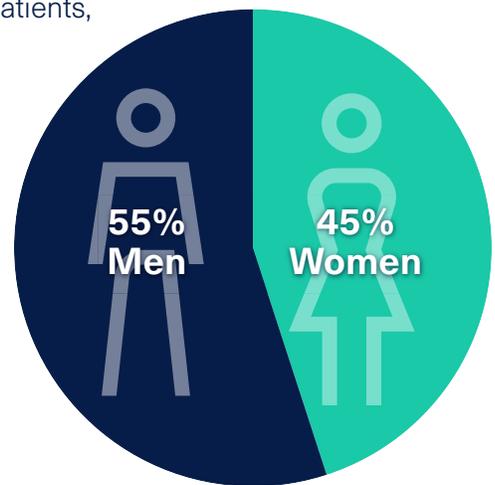


## 2. What patients were included in this study?

157 adult patients with psoriasis took part in the study. Of the 157 patients, 124 completed the study.

To participate in the study, patients had to have long-lasting moderate to severe plaque psoriasis, with or without psoriatic arthritis (inflammation of the joints) for at least 6 months. The patient's doctors also needed to agree they were eligible for treatment with systemic therapy (treatment that targets the whole body by circulating through the bloodstream) given as an injection under the skin with a syringe (needle).

There were more men (55%) than women (45%) in the study. Patient ages ranged from 19 to 79 years of age with an average age of 49 years.

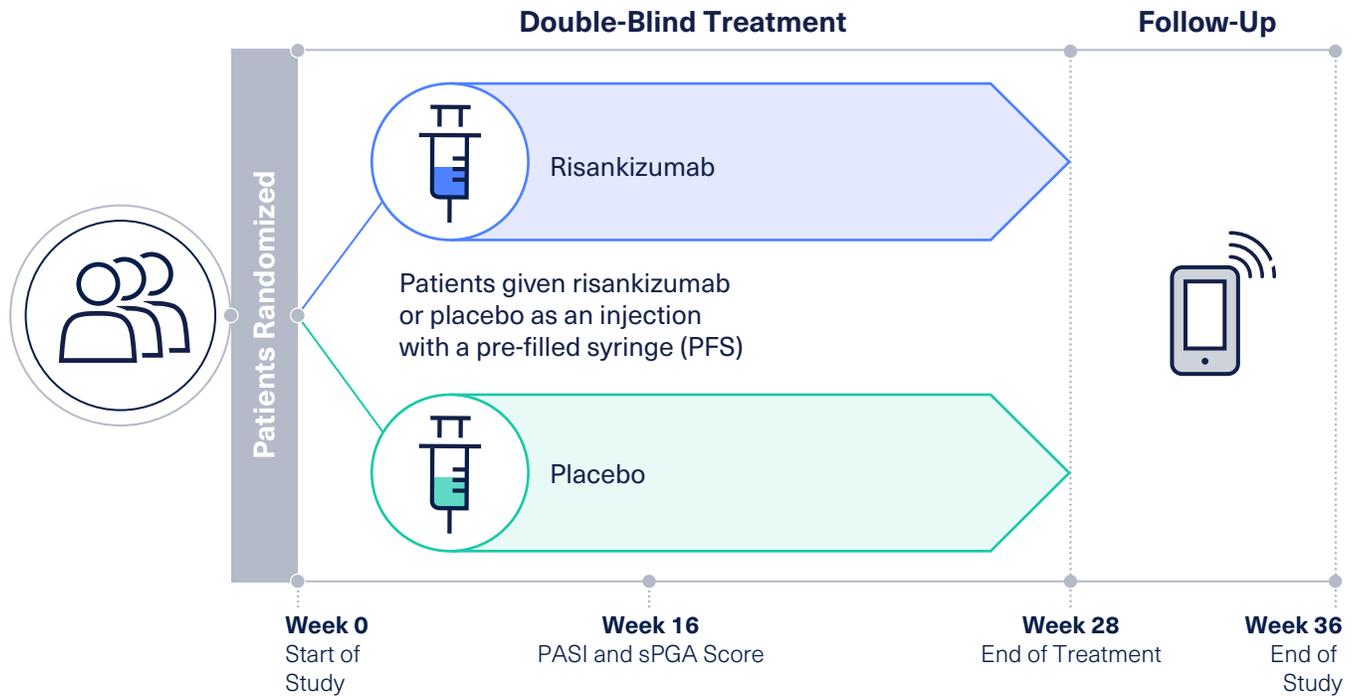


### 3. Which medicines were studied?

The medicine in this study was called risankizumab. Patients were randomly placed into two groups by a computer to receive treatment with either risankizumab or placebo given by a pre-filled syringe (PFS) as an injection under the skin. Treatment was double-blind which means that neither the patients nor the study doctors knew who was given which treatment.

All patients received training from medical professionals at Week 0 on how to properly administer treatment by PFS at Weeks 0, 4, and 16.

The diagram below shows how the study was organized.



During the study, patients' signs and symptoms of psoriasis were scored using the Psoriasis Area and Severity Index (PASI) and static Physician's Global Assessment (sPGA). PASI is commonly used to measure severity of psoriasis by assessing the amount of the body covered with psoriasis areas (lesions) and their redness, thickness and scaliness. The sPGA also measures the severity of skin lesions but does not factor in the amount of the body affected. The main goal of the study was to see how patients' signs and symptoms of psoriasis were after 16 weeks of treatment.

## 4. What were the side effects?

Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to study drug.

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.

No patients treated with risankizumab or placebo had serious side effects during the study.

No patient treated with risankizumab and 1 patient (1.9% of patients) treated with placebo stopped taking the study drug because of the side effect of an infection of the large intestine during the study.

No patient treated with risankizumab or placebo died during the study.

5.7% of patients (6 patients) treated with risankizumab and 3.8% of patients (2 patients) treated with placebo had side effects during the study. The table below shows information about the common side effects (in at least 2 or more patients) in either group. The most common side effects in either group were nausea and stuffy nose (nasal congestion).

	Risankizumab (105 Patients)	Placebo (52 Patients)
Number of patients with at least one side effect	6 (5.7% of patients)	2 (3.8% of patients)
Common Side Effects		
• Nausea	3 (2.9%)	1 (1.9%)
• Stuffy nose	2 (1.9%)	0 (0.0%)

## 5. What were the overall results of the study?

The study was completed as planned. The main goal of the study was to find out if treatment with a new formulation of risankizumab improved psoriasis symptoms better than placebo. Symptom improvement was based on PASI and sPGA scores after 16 weeks of treatment compared to the scores before treatment.

The results of this study showed that patients who took risankizumab had fewer signs and symptoms at Week 16 compared to patients who took placebo.

**PASI:** 62.9% of patients (66 patients) who took risankizumab and 3.8% of patients (2 patients) who took placebo achieved a 90% or more reduction in their symptoms of psoriasis. This means that areas of psoriasis were less severe and/or psoriasis covered smaller areas of their body than before starting treatment.

**sPGA:** 78.1% of patients (82 patients) who took risankizumab and 9.6% of patients (5 patients) who took placebo achieved a sPGA score of clear or almost clear. This means that their body had no or limited signs of 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?

This study showed that the new formulation of risankizumab is safe and effective for patients with plaque psoriasis and provides greater improvement in psoriasis signs and symptoms when compared to placebo.

This summary only shows the results from this study, which may be different from the results of other studies.

## 7. Are there any plans for future studies?

Multiple risankizumab studies are ongoing for a wide range of conditions.

## 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 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Risankizumab Using a New Formulation for the Treatment of Adult Subjects With Moderate to Severe Plaque Psoriasis
Protocol Number	M15-999
Clinicaltrials.gov	NCT03875482 <a href="https://clinicaltrials.gov/ct2/show/NCT03875482?term=M15-999&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03875482?term=M15-999&amp;draw=2&amp;rank=1</a>
Study Sponsor	AbbVie, Inc. Phone: +1 800-633-9110 Email: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

## 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!

