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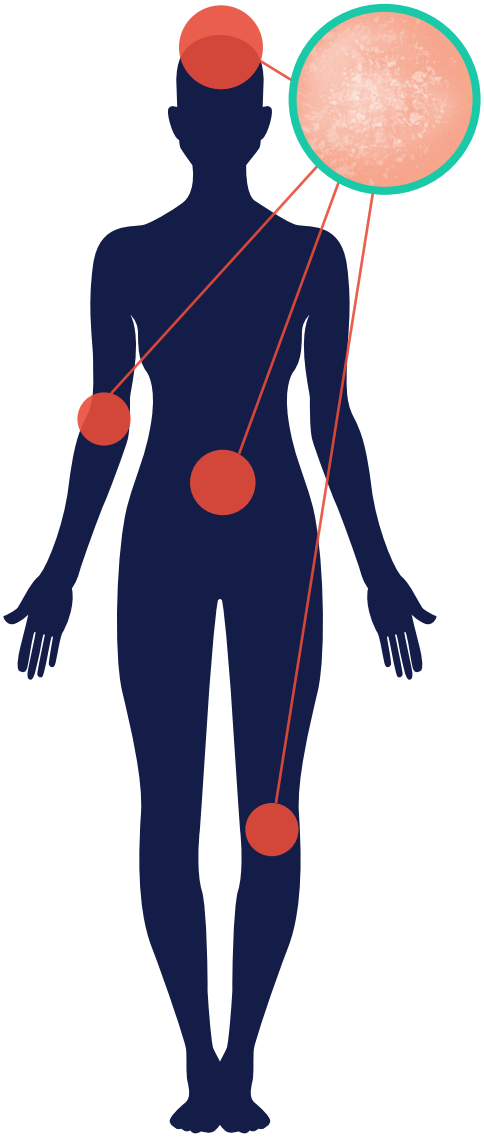
Summary of Clinical Trial Results

For Laypersons

A study to learn how effective and safe a medicine containing the study drug risankizumab works to treat adult patients with moderate to severe long-lasting plaque psoriasis

Overall Summary

- Psoriasis is a skin disorder which causes the skin cells to multiply faster (almost 10 times) than normal, making it 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 from November 2014 to September 2018 in 4 countries.
- Patients who completed the previous lead-in study and met the requirements of this extension study were selected to participate.
- A total of 110 adult patients took part in this study and 99 completed the study.
- This study showed that risankizumab was well-tolerated in longer durations (up to 48 months).
- 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 long-term benefits and safety in patients with moderate to severe psoriasis.

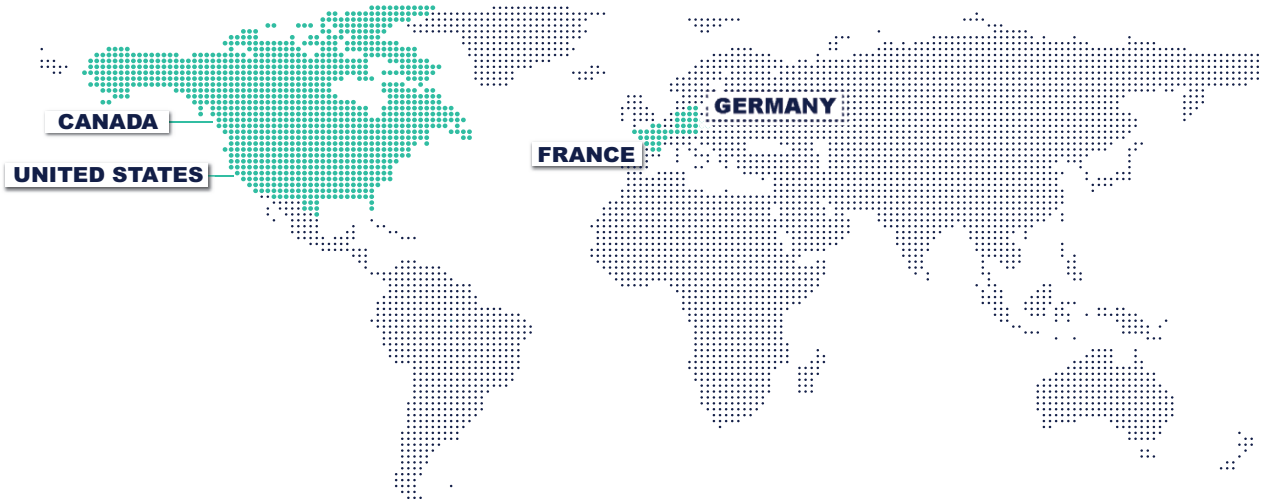
Researchers planned this Phase 2 study as an extension of a previous study (the lead-in study). Phase 2 studies test potential new treatments in a small number of patients with a condition or disease. This study was "open-label", which means that both the patients and the study doctors knew which treatments were given. Patients who had successfully completed the lead-in study and met the requirements for this study had the option to enter this extension study.

In this study, the study doctors looked at the safety and benefits of risankizumab 90 milligrams (mg) in patients with moderate to severe plaque psoriasis. Study drug dose was increased to 180 mg if poor clinical results were found with the previous dose (90 mg). The study doctors also reported any side effects the patients may have had during and after treatment with risankizumab.

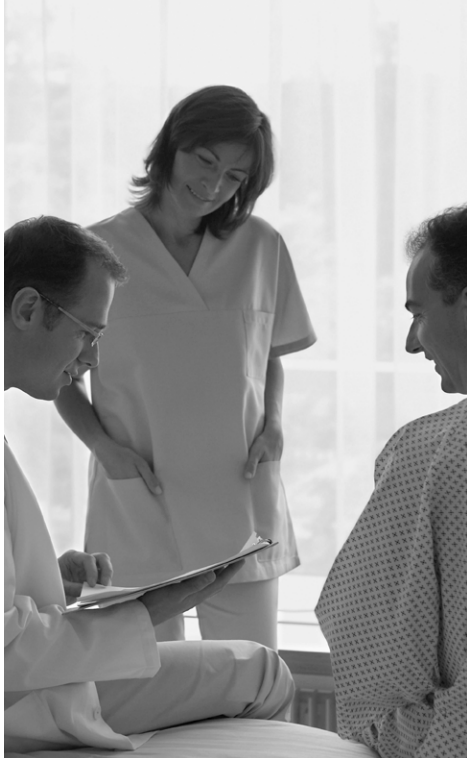
The main aim of the study was to find out how safe and beneficial risankizumab is in long-term use in patients with moderate to severe plaque psoriasis. This summary only includes the results of this study, which may be different from the results of other studies.

1.2 When and where was this study done?

This study took place from November 2014 to September 2018 in the following locations:

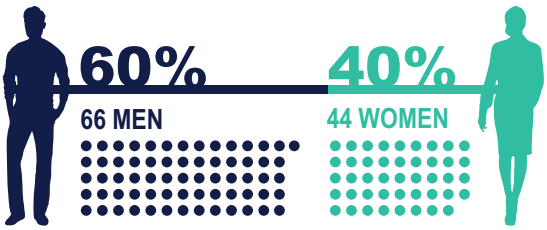


2. What patients were included in this study?



A total of 110 patients took part in the study who were identified with moderate to severe long-lasting plaque psoriasis. Among the 110 patients, 99 completed the study and 11 did not: 6 patients left the study by personal choice, 4 were lost to follow-up (patient[s] did not return to continue treatment or testing), and 1 patient did not complete the study due to other reasons.

There were more men (60%) than women (40%) in the study. Study doctors selected only adults to participate in this study. Patients ranged from 22 to 73 years of age. Most patients did not have a history of other linked disorders, such as psoriatic arthritis or heart problems.



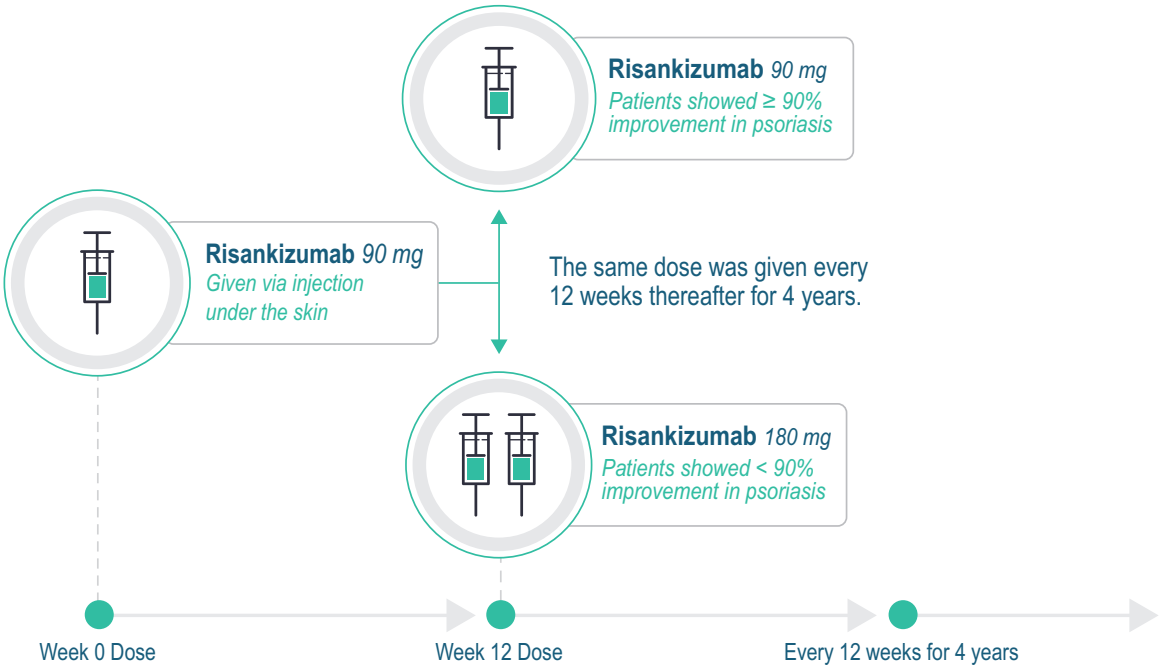
3. Which medicines were studied?

This study was an extension of a lead-in study. Patients who had successfully completed the lead-in study and met the requirements for this study had the choice to enter this study. Patients' last visit of the lead-in study was considered the first visit (Week 0) of this study.

The medicine in this study was risankizumab, given via injection under the skin. The first dose of risankizumab was 90 mg, given at the first visit in Week 0. Doctors decided to give patients either 90 mg risankizumab or a higher dose of 180 mg (2 injections of 90 mg risankizumab) at Week 12. The dose given at Week 12 was selected by doctors on the basis of improvement in psoriasis symptoms. Doctors looked at each patient's physical symptoms of psoriasis such as redness, scaling, and wound thickness to measure severity. Patients who showed 90% or greater improvement in psoriasis on the Psoriasis Area and Severity Index (PASI90) were given risankizumab 90 mg on Week 12 and every 12 weeks thereafter for 4 years. Patients who showed less than 90% improvement on the PASI90 were switched to receive a dose of 180 mg risankizumab instead on Week 12 and every 12 weeks thereafter for 4 years.

A 12-week follow-up was conducted to check the patient's overall health after the end of treatment. Doctors examined the patient's safety by checking side effects throughout the study and 12 weeks afterward in the follow-up period.

The diagram below displays how different doses 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 study drug.

About 12.7% of patients (14 patients) had serious side effects; of these, 1.8% of patients (2 patients) had related serious side effects during the study. Both patients with related serious side effects belonged to the risankizumab 90 mg group. One patient had 2 different types of skin cancer that were considered mild by doctors. Another patient had moderate cystitis (swelling of the bladder), pyelonephritis (swelling of the kidneys), and sepsis (bodily reaction to an infection).

No deaths were reported during this study. No patient left the study as a result of side effects.

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

	OVERALL (n=110)
Number of patients with related serious side effects	2 (1.8% of patients)
Number of patients who stopped taking part because of side effects	0 (0% of patients)
Number of patients with related side effects leading to death	0 (0% of patients)

About 77.3% of patients (85 patients) had side effects during the study; of these, 13.6% of patients (15 patients) had a side effect considered related to study drug.

The table below shows information about most common related side effects (in 2 or more patients) in this study. The most common related side effects were upper respiratory tract infection (infection of the nose, throat, and airways) in 3.6% of patients (4 patients) and influenza (flu) in 2.7% of patients (3 patients).

	OVERALL (n=110)
Number of patients with at least one related side effect	15 (13.6% of patients)
Side Effects	
Upper respiratory tract infection (infection of the nose, throat, and airways)	4 (3.6% of patients)
Influenza (flu)	3 (2.7% of patients)
Injection site erythema (redness at the injection spot)	2 (1.8% of patients)
Cystitis (swelling of the bladder)	2 (1.8% of patients)
Nasopharyngitis (cold)	2 (1.8% of patients)
Sinusitis (swelling of sinuses)	2 (1.8% of patients)

5. What were the overall results of the study?

The study was completed as planned. Researchers throughout this study aimed to find out if risankizumab worked effectively and safely to treat moderate to severe plaque psoriasis over a long period of time.

Study doctors determined the safety of patients throughout the study and in the 12-week follow-up period after treatment. Doctors kept a record of every side effect whether related or unrelated to risankizumab. It was found that about 77.0% of patients (67 patients) who received risankizumab 90 mg had side effects. About 13.8% of these patients (12 patients) had related side effects. While 78.3% of patients (18 patients) who received risankizumab 180 mg had side effects. About 13.0% of these patients (3 patients) had related side effects.

Serious side effects were experienced by 13.8% of patients (12 patients) who received risankizumab 90 mg and 8.7% of patients (2 patients) who received risankizumab 180 mg. Most side effects were mild to moderate. Doctors found risankizumab to be well-tolerated in this long-term study.

Doctors assessed whether patients receiving risankizumab were able to achieve a 90% reduction in the Psoriasis Area Severity Index score (PASI90), which measures improvement in symptoms of psoriasis. Doctors measured these results at Week 48 of this extension study by studying 4 treatment groups from the lead-in study: risankizumab 18 mg; risankizumab 90 mg; risankizumab 180 mg; and ustekinumab 45 mg or 90 mg. Doctors used these lead-in study groups to measure changes in results over time. All patients later received risankizumab 90 mg or 180 mg during this open-label extension study at Week 12 and every 12 weeks for 4 years

These results show that the percentage of patients with a PASI90 score during the lead-in study was generally maintained or improved during this extension study.

	Risankizumab 18mg → Risankizumab 90/180	Risankizumab 90mg → Risankizumab 90/180	Risankizumab 180mg → Risankizumab 90/180	Risankizumab 45mg or 90mg → Risankizumab 90/180
Percentage of patients with a PASI90 score at week 48	**72.7% (16 patients)**	**77.8% (21 patients)**	**71.9% (23 patients)**	**74.1% (20 patients)**

6. How has the study helped patients and researchers?

These results helped the researchers learn the safety and benefits of risankizumab in the long-term 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?

Patients may be transferred from this open-label extension study to Study M15-997, which is also an open-label extension study.

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	An Open Label Extension Trial Assessing the Safety and Efficacy of BI 655066/ABBV-066/Risankizumab Administered Subcutaneously in Patients with Moderate to Severe Chronic Plaque Psoriasis
Protocol Number	M16-009 (1311.13)
ClinicalTrials.gov	NCT02203851 https://clinicaltrials.gov/ct2/show/NCT02203851
EudraCT	2014-001687-36 https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-001687-36/FI
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.