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# Summary of Clinical Trial Results

*For Laypersons*

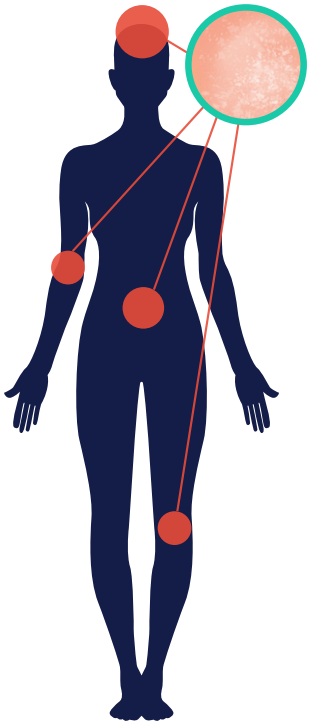
**A study to learn how effective and safe a medicine containing the study drug risankizumab is compared to placebo (no medicine) to treat adult patients with moderate to severe long-lasting plaque psoriasis after initial treatment, withdrawal, relapse, and re-treatment**

## 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.
- In this study, doctors compared the effects and safety of risankizumab to placebo (no medicine) in patients with moderate to severe long-lasting plaque psoriasis.
- The study took place from February 2016 to July 2018 in 9 countries.
- The study was planned as a 2-part study, where Part A was defined as an introduction and response period and Part B as the withdrawal and re-treatment period.
- A total of 507 adult patients took part in this study and 443 completed the study.
- This study showed benefits of taking risankizumab compared to placebo in treating moderate to severe long-lasting plaque psoriasis.
- This study also showed that patients who responded to risankizumab then stopped taking risankizumab, and as a result relapsed, could benefit from beginning risankizumab again.
- The percent of patients who had side effects during the study was similar between the groups that received risankizumab and placebo.
- 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 too fast and lead to psoriasis in some people.

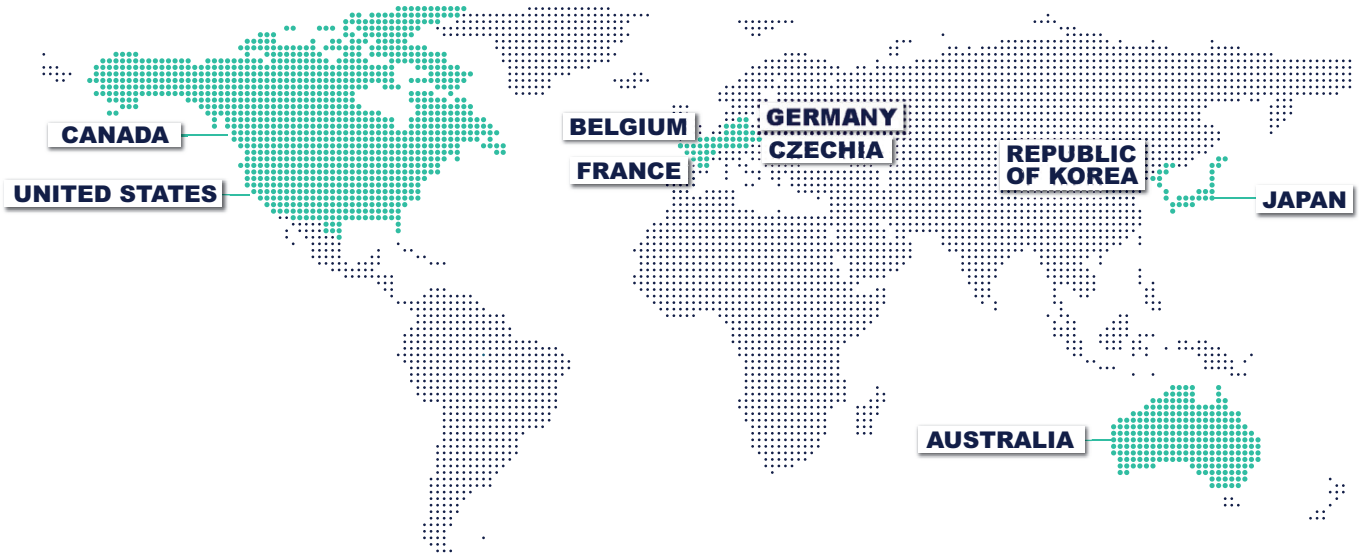
There is no cure for psoriasis, but treatment relieves the symptoms. Researchers are looking for a treatment that prevents rapid cell multiplication caused by psoriasis by weakening the activity of the immune system. Many drugs with this ability have been tested in other studies. In this study, a new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

Researchers planned this Phase 3 study in patients with moderate to severe long-lasting plaque psoriasis. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. This study was also "double-blinded", which means that neither the patients nor the study doctors knew who was given which study drug. This ensures that no study results were influenced. However, some parts of this study were also "open-label", which means that both the patients and the study doctors knew which treatments were given to protect patients' safety and wellbeing, without jeopardizing the main study objectives. A computer program was used to randomly choose the treatment each participant was given. This process is called "randomization", which helps make the groups equal and reduces the differences between the groups. Researchers do this so that comparing the results of each treatment is as accurate as possible.

The main aim of the study was to find out how safe and beneficial risankizumab is compared to placebo in patients with long-lasting moderate to severe plaque psoriasis. Placebo looks like risankizumab but contains no real medicine. Researchers used a placebo to compare the results for patients who took risankizumab with the results for patients who took no medicine at all. Study doctors first looked at the benefits of risankizumab versus placebo at Week 16 of treatment. Study doctors also tested if the patient's response to risankizumab was retained after stopping the medicine. Moreover, the effect of risankizumab was assessed in patients whose psoriasis worsened after stopping the medicine when they re-treated. Lastly, the study doctors reported any side effects the patients may have had during and after treatment with the study drug. 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 the study done?

This study took place from February 2016 to July 2018 in the following locations:



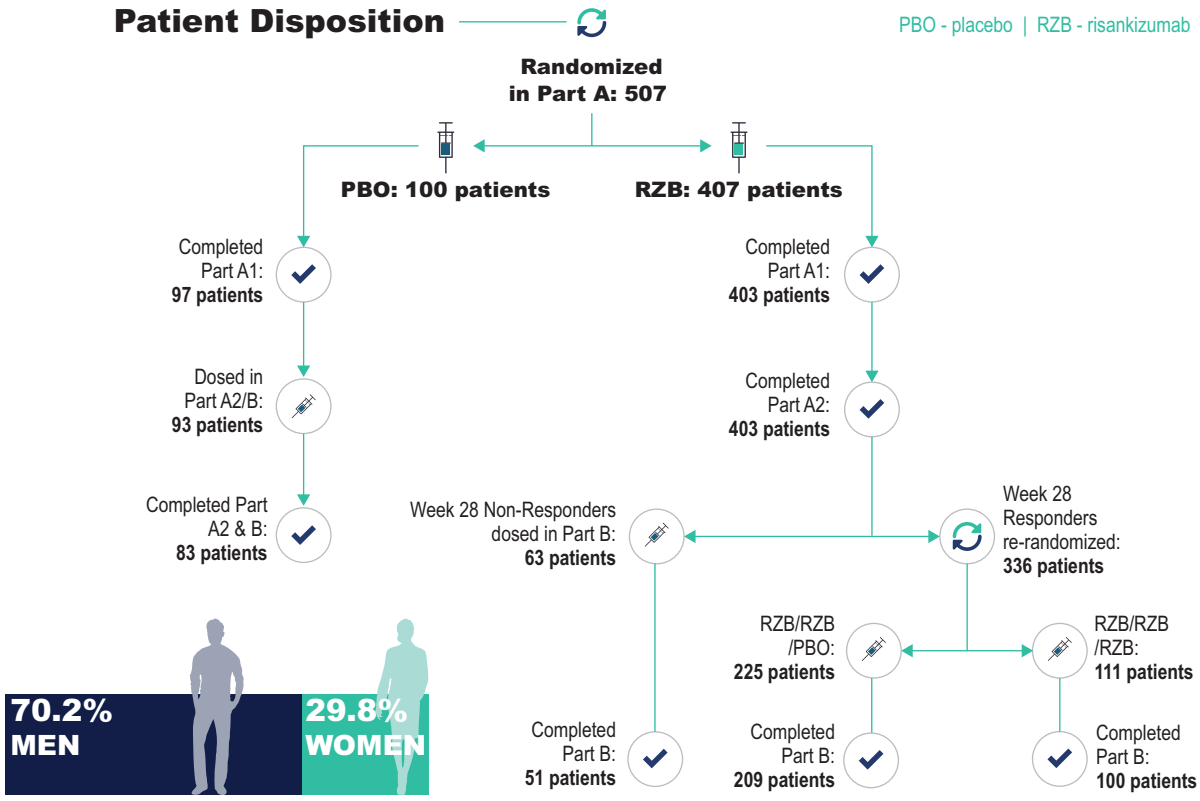

## 2. What patients were included in this study?

A total of 507 patients took part in the study. The study was divided into 2 parts (A and B). Part A was further divided into Part A1 and A2. In Part A1, which lasted for 16 weeks, 407 patients were randomly assigned to risankizumab and 100 patients were randomly assigned to placebo. A total of 97 of the 100 patients who took placebo completed Part A1, and then 83 of these patients completed Part A2 and B.

A total of 500 patients completed Part A1. In Part A2, which lasted for 12 weeks, all patients regardless of their Part A1 study drug received risankizumab. All 403 patients who received risankizumab in Part A1 completed Part A2, but 4 of these patients did not enter Part B afterwards.

In Part B, which lasted for 60 weeks, patients previously assigned to risankizumab in Part A1 were further divided into 2 groups based on their response to risankizumab at Week 28. Responders were patients whose symptoms improved to clear or almost clear. Non-responders were patients whose symptoms remained mild, moderate, or severe. A total of 63 patients did not respond to risankizumab (non-responders; 51 of whom completed the study) and 336 patients did respond to risankizumab (responders; 309 of whom completed the study). The patients who responded to risankizumab were randomly assigned to either risankizumab or placebo.

There were more men (70.2%) than women (29.8%) in the study. Study doctors selected only adults to participate in this study. Patients ranged from 19 to 80 years of age. More patients (78.9%) had moderate psoriasis than severe psoriasis (21.1%) at the start of the study.




## 3. Which medicines were studied?

The medicine in this study was risankizumab 150 milligrams (mg) or placebo, given via injection under the skin as described below:

| GROUPS | DESCRIPTION |
|---|---|
| **Part A1:**<br>**Placebo**<br>**Risankizumab** | At the start of the study, patients were randomized to receive either risankizumab or placebo at Week 0 and Week 4. |
| **Part A2/Part B:**<br>**Placebo/Risankizumab** | Patients who received placebo at the start of the study then received risankizumab at Week 16 (Part A2) and at Week 28 and every 12 weeks up to 88 weeks (Part B). |
| **Part A2:**<br>**Risankizumab/Risankizumab** | Patients who received risankizumab at the start of the study then received risankizumab at Week 16 (Part A2). |
| **Part B - Re-randomized responders:**<br>**Risankizumab/Placebo**<br>**Risankizumab/Risankizumab** | Patients who received risankizumab in Part A and were responders at Week 28 were then re-randomized to receive risankizumab or placebo at Week 28 and every 12 weeks up to Week 88 (Part B). |
| **Part B - Nonresponders:**<br>**Risankizumab/Risankizumab** | Patients who received risankizumab in Part A and were nonresponders at Week 28 received risankizumab at Week 28 and every 12 weeks up to 88 weeks (Part B). |

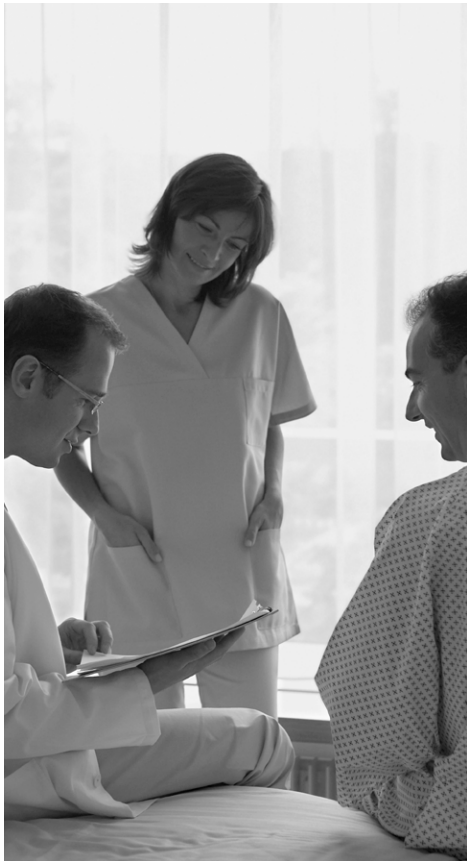
Note: Responders were patients whose symptoms improved to clear or almost clear. Non-responders were patients whose symptoms remained mild, moderate, or severe.

The study was divided into a 42-day screening period, 88-week treatment period, and 16-week follow-up. Before the study started, a screening period of 42 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.

The 88-week treatment period was divided into 2 parts that allowed for an introduction to the study drug and initial response period (Week 0 to Week 28) followed by a withdrawal and re-treatment period (Week 28 to Week 88).

A 16-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 16 weeks afterward in the follow-up period.

## 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 11.0% of patients who received risankizumab (55 patients) had serious side effects. The total number of patients who had serious side effects considered possibly related to risankizumab was 1.0% of patients (5 patients). About 2.4% of patients who received risankizumab (12 patients) left the study due to side effects. The total number of patients who left the study due to a side effect considered possibly related to risankizumab was 0.8% of patients (4 patients).

Three patients who received more than 1 dose of risankizumab died during the study; 1 patient died from seizures, 1 patient died due to liver cancer, and 1 patient died from unknown causes. One patient also died of unknown causes in the follow-up period. None of these deaths were considered related to risankizumab.

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

| | ALL RISANKIZUMAB (N=500 PATIENTS) |
|---|---|
| Number of patients with related serious side effects | **5 (1.0% of patients)**<br>***Serious Related Side Effects:*** *Abdominal pain, bacterial meningitis, sepsis (severe reaction to infection), arthralgia (joint pain), prostate cancer* |
| Number of patients who stopped taking part because of related side effects | **4 (0.8% of patients)**<br>***Reasons for stopping:*** *Dermatitis and perivascular dermatitis (skin irritation), worsening of psoriasis, arthralgia (joint pain), worsening of psoriatic arthritis* |
| Number of patients with related side effects leading to death | **0 (0% of patients)** |

About 85.2% of patients who received risankizumab (426 patients) had side effects. The total number of patients who had side effects considered possibly related to risankizumab was 17.2% of patients (86 patients).

The table below shows information about the most common related side effects (in 4 or more patients) in this study. The most common related side effect was upper respiratory tract infection.

| | ALL RISANKIZUMAB (N=500 PATIENTS) |
|---|---|
| Number of patients with at least one related side effect | 86 (17.2% of patients) |
| **Side Effects** | |
| Upper respiratory tract infection | 13 (2.6% of patients) |
| Injection site erythema (redness) | 6 (1.2% of patients) |
| Nasopharyngitis (common cold) | 8 (1.6% of patients) |
| Pruritus (itchy skin) | 5 (1.0% of patients) |
| Headache | 5 (1.0% of patients) |
| Alopecia (hair loss) | 4 (0.8% of patients) |
| Sinusitis (sinus infection) | 4 (0.8% of patients) |
| Diarrhea | 4 (0.8% 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 when compared to a placebo to treat long-lasting plaque psoriasis.

Doctors assessed whether patients receiving risankizumab or placebo were able to achieve a 90% reduction in the Psoriasis Area and Severity Index score (PASI90), which measures improvement in symptoms of psoriasis. It was found that the patients in the study groups who received risankizumab had fewer signs of plaque psoriasis at Week 16 (Part A1) compared to patients who had taken placebo. About 73.2% of patients who received risankizumab achieved a 90% or more reduction in their symptoms of plaque psoriasis. Whereas 2.0% of patients who received placebo showed a 90% or more reduction in their symptoms of plaque psoriasis. These results show that risankizumab achieved better improvement in disease compared to placebo.

Study doctors tested disease severity by using the Static Physician's Global Assessment score (sPGA) at Week 16 (Part A1). It was found that 83.5% of patients in the risankizumab group, compared to 7.0% of patients in the placebo group, saw psoriasis symptoms improve to clear or almost clear. Again, these results show that risankizumab achieved better improvement in disease compared to placebo.

Study doctors also tested disease severity using the sPGA score at Week 52 (Part B). This was done to test the treatment effects after reassignment on the basis of response at Week 28. At Week 52, it was found that 87.4% of patients treated with risankizumab had maintained clear or almost clear skin, compared to 61.3% of patients treated with placebo.

Study doctors again tested disease severity using the sPGA score at Week 104 (Part B). This was done to test the long-lasting treatment effects after reassignment on the basis of response at Week 28. At Week 104, it was found that 81.1% of patients treated with risankizumab had maintained clear or almost clear skin, compared to 7.1% of patients treated with placebo.

One hundred fifty-three (153) patients whose psoriasis came back after stopping risankizumab were evaluated at Week 16 of re-treatment. About 83.7% regained sPGA of clear or almost clear, which was a similar response as after initial treatment. Re-treatment with risankizumab was found to be successful for a majority of these patients.

## 6. How has the study helped patients and researchers?

These results helped the researchers learn the safety and benefits of risankizumab compared with placebo. They also learned that risankizumab is well-tolerated. Findings from this study may be used in other studies to learn whether patients are helped by risankizumab.

This summary only shows the results from 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 the treatment based on the results of a single study.

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

There are currently plans for future studies in this patient population that include the medicine that was used in this study.

## 8. Who sponsored this study?

This study was sponsored by Boehringer Ingelheim and 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** | BI 655066 / ABBV-066 (Risankizumab) Versus Placebo In a Multicenter Randomized Double-blind Study in Patients With Moderate to Severe Chronic Plaque Psoriasis Evaluating the Efficacy and Safety With Randomized Withdrawal and Retreatment (IMMhance) |
| **Protocol Number** | M15-992 (1311.4) |
| **ClinicalTrials.gov** | NCT02672852<br>https://clinicaltrials.gov/ct2/show/study/NCT02672852?term=M15-992&rank=1 |
| **EudraCT** | 2014-005102-38<br>https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-005102-38/DE |
| **Study Sponsor** | Global Medical Services, AbbVie<br>Phone: 800-633-9110<br>Email: abbvieclinicaltrials@abbvie.com |

19Sep2019. 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!**