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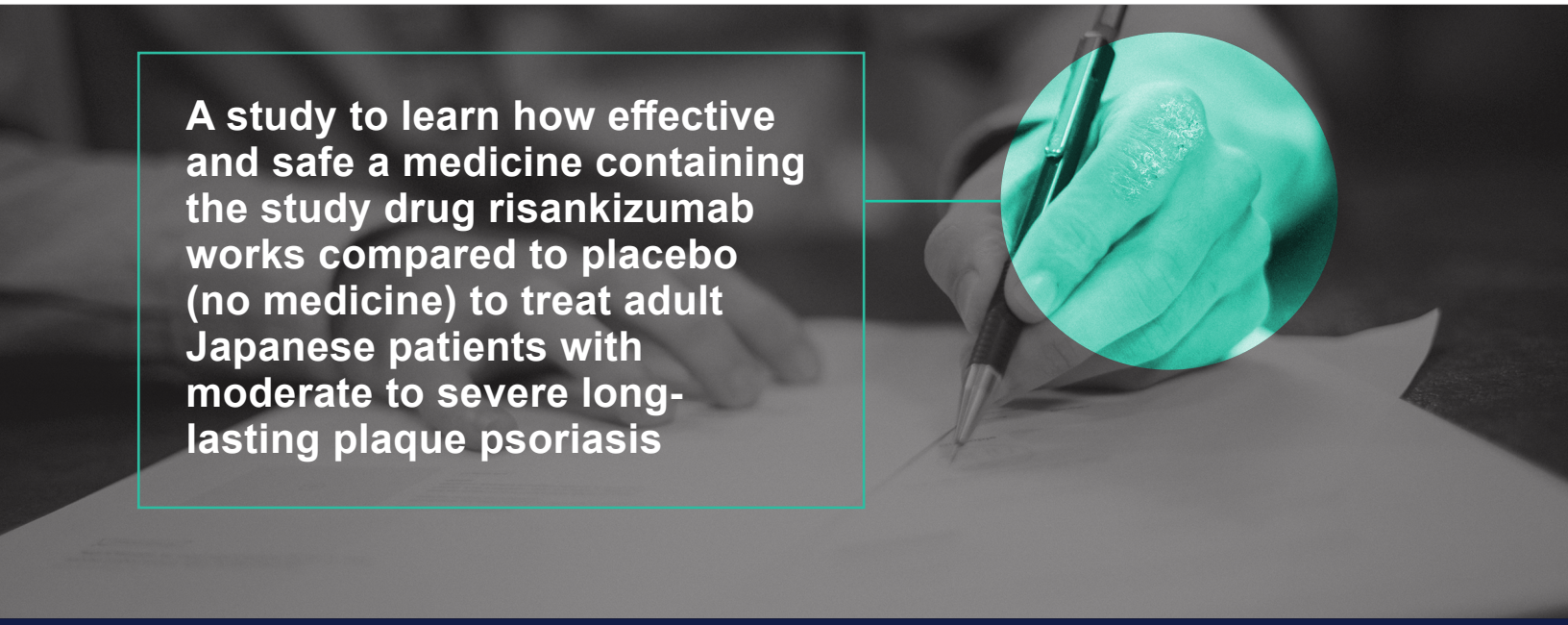
Summary of Clinical Trial Results

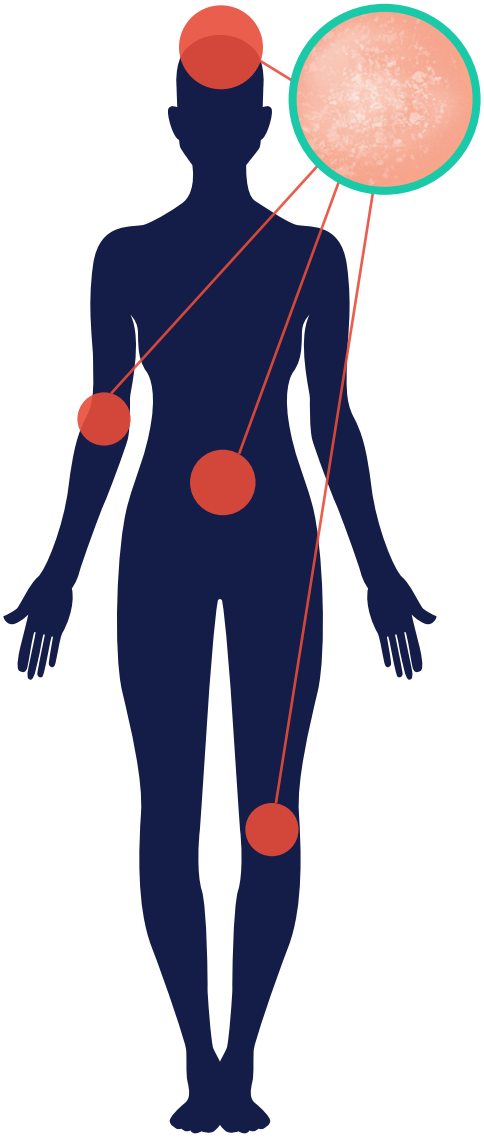
For Laypersons



A study to learn how effective and safe a medicine containing the study drug risankizumab works compared to placebo (no medicine) to treat adult Japanese 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 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 Japan from December 2016 to June 2018.
- In this study, study doctors compared the effects and safety of risankizumab with placebo (no medicine) in patients with moderate to severe long-lasting plaque psoriasis.
- A total of 171 adult patients took part in the study. There were two parts of the study: Part A and Part B. A total of 167 patients finished Part A of the study and moved on to Part B. A total of 163 patients then finished Part B.
- This study showed the long-term effects of taking risankizumab compared to placebo for moderate to severe plaque psoriasis.
- The number of side effects was similar to what was expected in these 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 placebo.

Researchers planned this Phase 2/3 study in patients with moderate to severe long-lasting plaque psoriasis. Phase 2 and 3 studies test potential new treatments in small and large numbers 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.

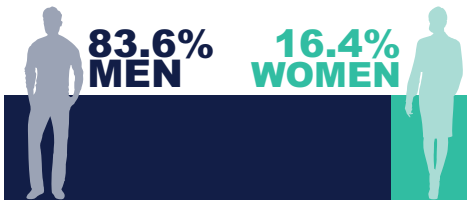
Doctors looked at the benefits of two different doses of risankizumab versus placebo at Week 16 of treatment. Placebo looks like risankizumab but contains no real medicine. Researchers use placebos in studies to compare the results for patients who take study drugs with the results for patients who take no medicine at all. The study doctors also reported any side effects patients may have had during and after treatment with the study drug.

The main aim of the study was to determine the efficacy and safety of risankizumab for patients with moderate to severe long-lasting 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 December 2016 to June 2018 in Japan.

2. What patients were included in this study?



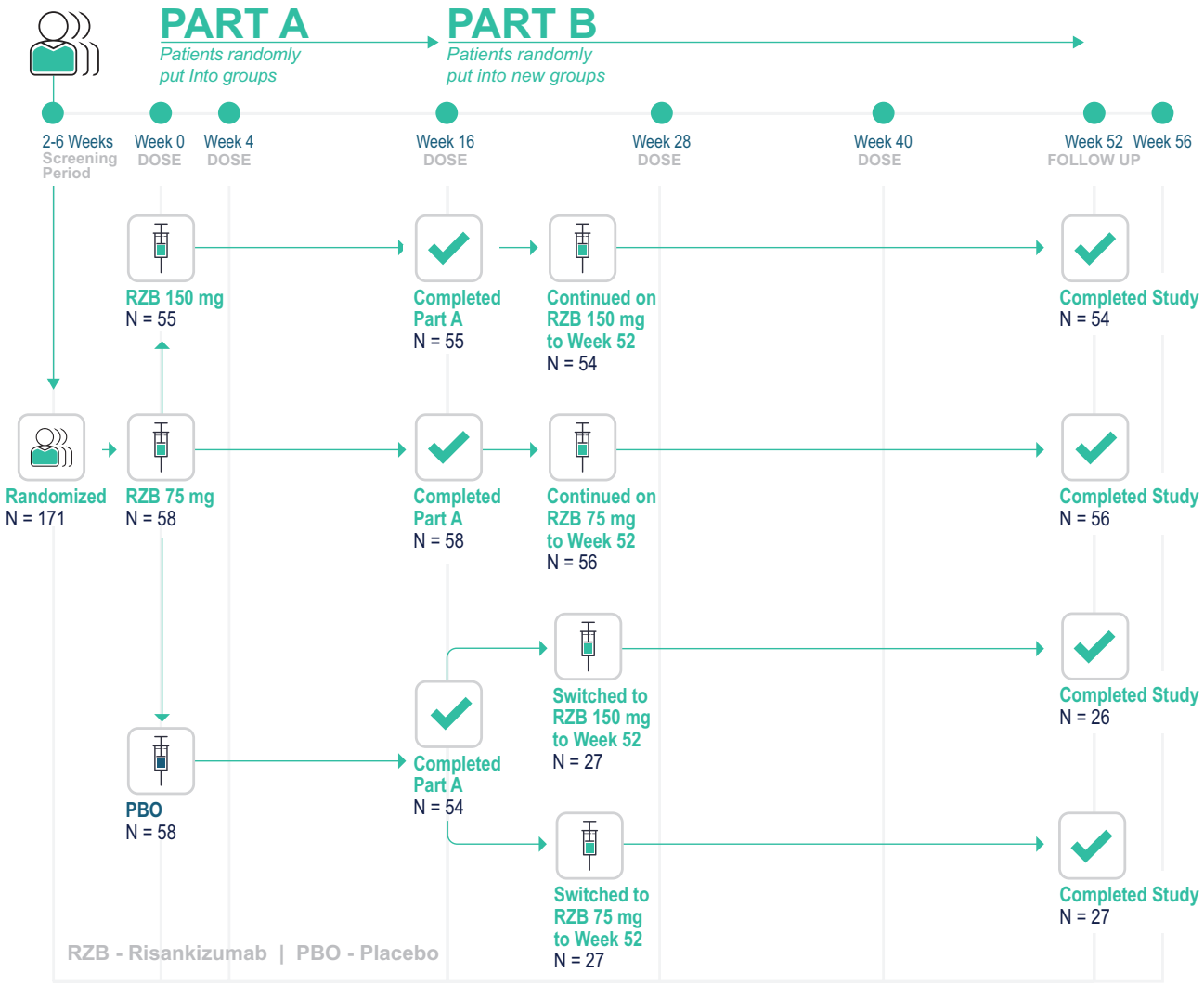
A total of 171 adult patients took part in the study. All of the patients had moderate or severe plaque psoriasis for at least 6 months. Patients who had previously tried the study drug were not included in this study.

There were two parts of the study: Part A and Part B. A total of 167 patients finished Part A of the study and moved on to Part B. A total of 163 patients then finished Part B. In Part A, patients were randomly split into 3 groups by treatment: placebo, risankizumab 75 milligrams (mg), and risankizumab 150 mg. After 16 weeks, those who completed Part A moved on to Part B, where they were either given risankizumab 75 mg or risankizumab 150 mg depending on which groups they were in in Part A.

There were more men (83.6%) than women (16.4%) in the study. Study doctors selected only adults to participate in this study. Patients ranged from 23 to 80 years of age.

3. Which medicines were studied?

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



The study was divided into a 2 to 6 week screening period, a 52 week treatment period, and a 4 week follow-up period.

Before the study started, a screening period of 2 to 6 weeks 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 3 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.

In Part A, study doctors gave the patients injections of the medicine, or placebo (no medicine), depending on which group they were in. Study doctors gave 2 injections under the skin to each patient at the start of the study (Week 0) and Week 4. The patients in the placebo group got 2 injections, but these did not contain any medicine. The patients in the risankizumab 75 mg group got one injection of risankizumab 75 mg and one injection of placebo. The patients in the risankizumab 150 mg group got 2 injections of risankizumab 75 mg. The patients did not know which dose of the drug they were given.

In Part B, the patients who got risankizumab (75 mg or 150 mg) in Part A continued to receive the same medicine. Patients who got placebo in Part A switched to risankizumab in Part B. Half of the patients got risankizumab 75 mg and an injection of placebo and the remaining half got risankizumab 150 mg via 2 injections of risankizumab 75 mg. Injections were given at Week 16, Week 28, and Week 40.

After the last dose of study drug, a 4 week follow-up was conducted to check the patient's overall health. Doctors examined the patient's safety by checking side effects throughout the study and 4 weeks afterward in the follow-up period. Patients could then either end their study participation or enter the open-label extension study (Study M15-997).

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.

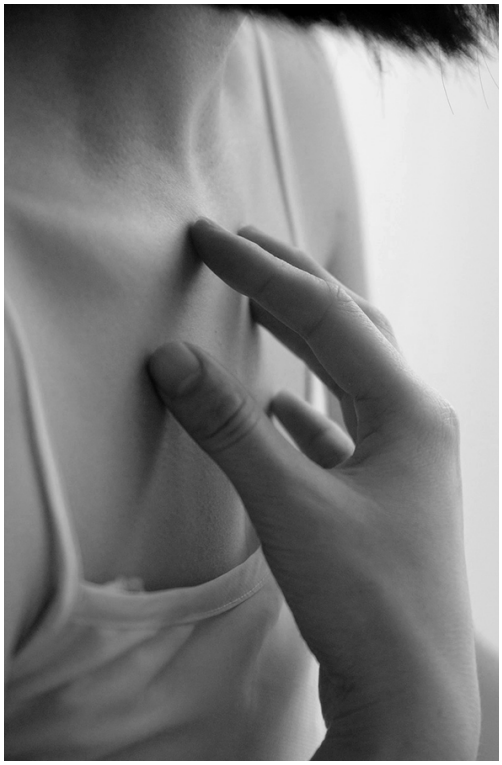
The table below shows information about the related serious side effects patients had in different parts of the study, as well as related side effects patients had that led to the patient stopping the study drug, and related side effects leading to death.

	PART A			PART B			
	PLACEBO N=58 patients	**RISANKIZUMAB** 75 mg N=58 patients	**RISANKIZUMAB** 150 mg N=55 patients	**PLACEBO/ RISANKIZUMAB** 75 mg N=27 patients	**PLACEBO/ RISANKIZUMAB** 150mg N=27 patients	**RISANKIZUMAB** 75 mg **/RISANKIZUMAB** 75 mg N=56 patients	**RISANKIZUMAB** 150 mg **/RISANKIZUMAB** 150 mg N=54 patients
Number of patients with related serious side effects	1 (1.7% of patients)	1 (1.7% of patients)	1 (1.8% of patients)	1 (3.7% of patients)	0	0	1 (1.9% of patients)
Side Effect	Pneumonia bacterial	Hypotension (low blood pressure)	Acute myocardial infarction (heart attack)	Rectal cancer	N/A	N/A	Rectal polyp (growth)
Number of patients who stopped taking part because of related side effects	0	0	0	0	0	0	0
Number of patients with related side effects leading to death	0	0	0	0	0	0	0

The table below shows information about the most common related side effects in this study (in 3.0% or more patients). The most common related side effect was nasopharyngitis (common cold).

	PART A			PART B			
	PLACEBO N=58 patients	**RISANKIZUMAB** 75 mg N=58 patients	**RISANKIZUMAB** 150 mg N=55 patients	**PLACEBO/ RISANKIZUMAB** 75 mg N=27 patients	**PLACEBO/ RISANKIZUMAB** 150mg N=27 patients	**RISANKIZUMAB** 75 mg **/RISANKIZUMAB** 75 mg N=56 patients	**RISANKIZUMAB** 150 mg **/RISANKIZUMAB** 150 mg N=54 patients
Number of patients with at least one related side effect	4 (6.9% of patients)	10 (17.2% of patients)	7 (12.7% of patients)	7 (25.9% of patients)	6 (22.2% of patients)	6 (10.7% of patients)	7 (13.0% of patients)
Nasopharyngitis (common cold)	0	0	2 (3.6% of patients)	1 (3.7% of patients)	2 (7.4% of patients)	2 (3.6% of patients)	1 (1.9% of patients)
Malaise (discomfort)	0	0	0	1 (3.7% of patients)	0	0	0
Influenza (flu)	0	0	0	1 (3.7% of patients)	0	0	0
Oral Herpes (cold sores)	0	0	0	0	1 (3.7% of patients)	0	0
Pharyngitis (swelling of back of throat)	0	1 (1.7% of patients)	0	0	1 (3.7% of patients)	1 (1.8% of patients)	0
Skin Bacterial Infection	0	0	0	0	1 (3.7% of patients)	0	0
Tinea Pedis (Athlete's foot)	0	1 (1.7% of patients)	0	0	1 (3.7% of patients)	0	0
Tonsillitis (swelling of tonsils)	0	0	0	0	1 (3.7% of patients)	0	0
Weight Increased	1 (1.7% of patients)	0	0	0	1 (3.7% of patients)	0	1 (1.9% of patients)
Rectal Cancer	0	0	0	1 (3.7% of patients)	0	0	0
Skin Papilloma (lump)	0	1 (1.7% of patients)	0	1 (3.7% of patients)	0	0	0
Eczema	0	1 (1.7% of patients)	0	0	1 (3.7% of patients)	0	0
Pruritus (itchy skin)	0	0	1 (1.8% of patients)	1 (3.7% of patients)	o	0	0
Urticaria (hives)	0	0	0	1 (3.7% of patients)	0	0	0

5. What were the overall results of the study?



The study was completed as planned. Researchers throughout this study aimed to find out if the study drug worked effectively and safely when compared to a placebo to treat plaque psoriasis.

To find out the main results of the study, doctors assessed whether patients receiving risankizumab or placebo 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 after 16 weeks of treatment compared to patients who had received placebo. About 75.9% of patients who received the 75mg dose of risankizumab and 74.5% of patients who received the 150mg dose of risankizumab achieved a 90% or more reduction in their symptoms of plaque psoriasis. Whereas about 1.7% of patients who received placebo 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 over placebo in the treatment of plaque psoriasis. They also learned that similar to placebo, 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 plans for future studies of risankizumab in this patient population.

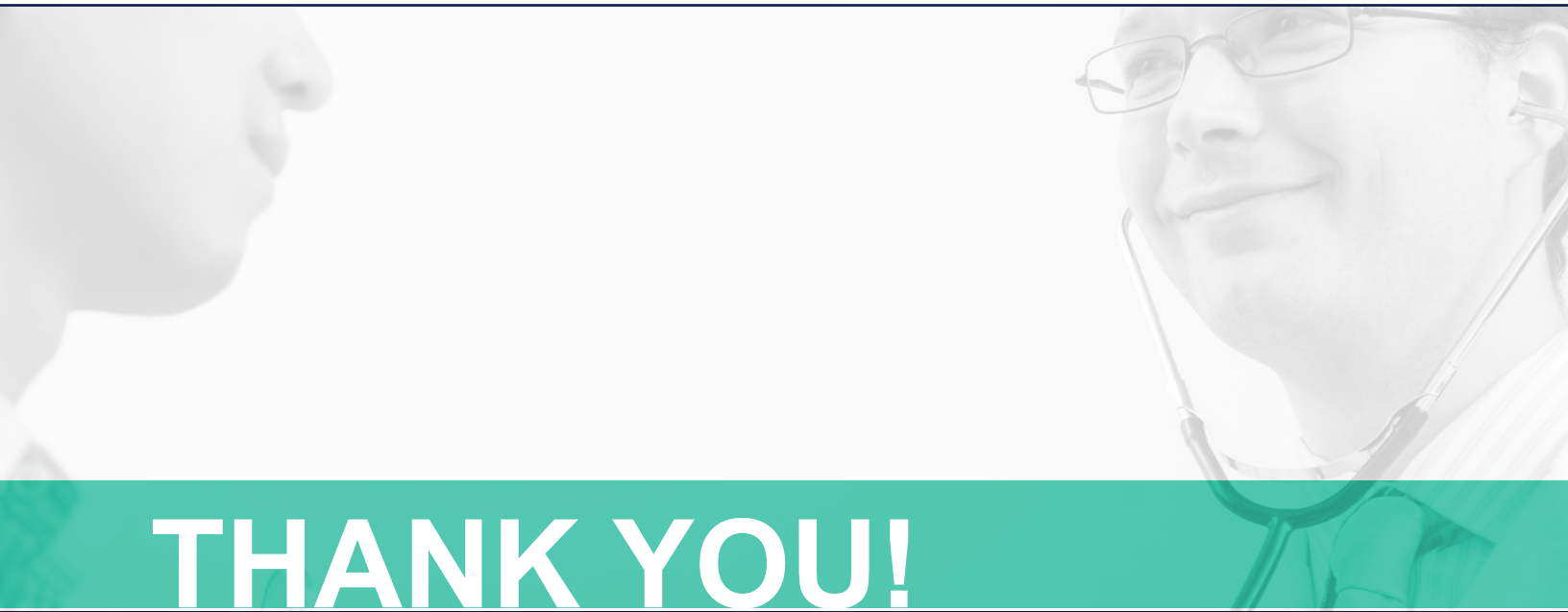
8. Who sponsored this study?

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 Phase II/III, Randomized, Double-blind Study to Evaluate Efficacy and Safety of Two Different Dose Regimens of BI 655066 (Risankizumab) and Placebo and Maintenance of Response of BI 655066 (Risankizumab) Administered Subcutaneously in Japanese Patients With Moderate to Severe Chronic Plaque Type Psoriasis
Protocol Number	M16-004 (1311.38)
ClinicalTrials.gov	NCT03000075 https://clinicaltrials.gov/ct2/show/results/NCT03000075?view=results
Study Sponsor	AbbVie Inc Phone: (800) 633-9110 Email: abbvieclinicaltrials@abbvie.com

06Aug2019. 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!