Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	Pfizer Inc.
Medicine(s) Studied:	Ritlecitinib (PF-06651600)
Protocol Number:	B7981037
Dates of Study:	15 September 2020 to 04 January 2022
Title of this Study:	A study to learn if ritlecitinib is safe in adult participants with patchy hair loss due to alopecia areata [A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study Investigating the Safety of Ritlecitinib (PF-06651600) in Adult Participants With Alopecia Areata]
Date(s) of this Report:	26 August 2022

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is alopecia areata?

Alopecia areata (AA) happens when signals from the immune system change the cycle of normal hair growth. The body attacks its own hair bulbs, and that leads to hair loss. Since the hair bulb remains intact, hair could regrow even though hair loss could come back.

AA can range from small spots of hair loss on the scalp to having total loss of hair on the scalp, face, and/or body.

AA can last for a long time. It can have a large impact on one's emotions, social life, and overall well-being.

What is ritlecitinib?

Ritlecitinib (rit-leh' sih-tih-nib) is a study medicine. It was not approved for general use at the time of this study.

Ritlecitinib comes as a 50-milligram (mg) tablet that is swallowed. Researchers think that ritlecitinib can help block the pathway of immune signals causing AA.

What was the purpose of this study?

This study wanted to learn if ritlecitinib was safe to take for participants with AA compared to placebo. A placebo does not have any medicine in it, but it looks like the study medicine.

- This study focused on finding out whether ritlecitinib has an effect on the hearing nerve. To find that out, study doctors measured how long it took for sound to travel from the ear to the brainstem (a part of the brain involved in hearing).
- This study also wanted to learn whether ritlecitinib has an effect on the nerve fibers in the skin. To find that out, study doctors looked at the amount and shape of nerve fibers in the skin.

Researchers wanted to know:

1. **Did ritlecitinib cause a change in the travel time of sound from the ear to the brainstem compared to placebo?**
2. **Did ritlecitinib cause a change in the amount and shape of nerve fibers in the skin compared to placebo?**

What happened during the study?

How was the study done?

Researchers tested ritlecitinib on a group of study participants. They wanted to find out if participants taking ritlecitinib had a change in:

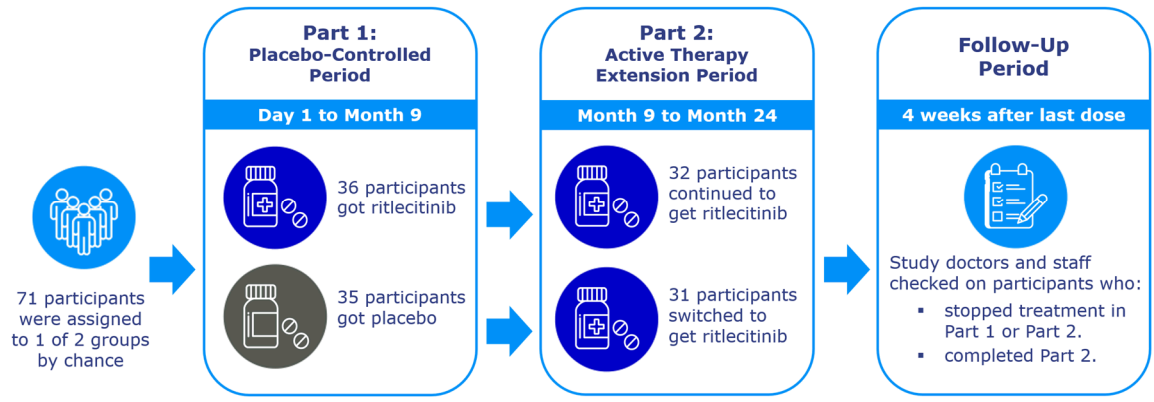
- the travel time of sound from the ear to the brainstem.
- the amount and shape of nerve fibers in the skin.

Researchers then compared the results of participants taking ritlecitinib to the results of participants taking placebo.

The participants and researchers did not know who took ritlecitinib and who took placebo. This is known as a "double-blind" study. The participants were assigned to each group by chance.

The figure below shows the parts of the study.

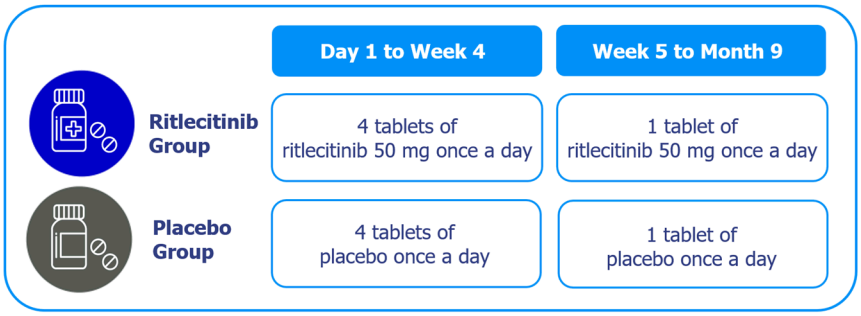
Figure 1. Parts of the study



This summary includes the results of all participants who entered Part 1.

The figure below shows the doses in Part 1.

Figure 2. Doses of the study treatment in Part 1



Where did this study take place?

This study took place in 27 centers in 4 countries: Poland, United States, Canada, and Australia.

When did this study take place?

It began on 15 September 2020. This summary includes the results through the end of Part 1 on 04 January 2022.

Who participated in this study?

The study included participants if they:

- were 18 to 50 years old.
- had hair loss due to AA on at least 25% (or one-fourth) of the scalp.

Participants were not allowed to join the study if they had certain medical conditions, for example:

- hearing loss or a disease that affected hearing.
- a disease of the brain or nerves.

In total, 71 participants started the study. A total of 21 men and 50 women participated.

Participants were to be treated for 9 months during Part 1.

- A total of 65 participants finished Part 1.
- Six (6) participants did not finish Part 1. The most common reasons were because participants could not be contacted for follow-up or due to their own choice to leave the study.

How long did the study last?

The participants were in Part 1 of the study for about 9 months. Part 1 of the study took about 15 months to finish. This is because participants started the study at different times.

When Part 1 ended in January 2022, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

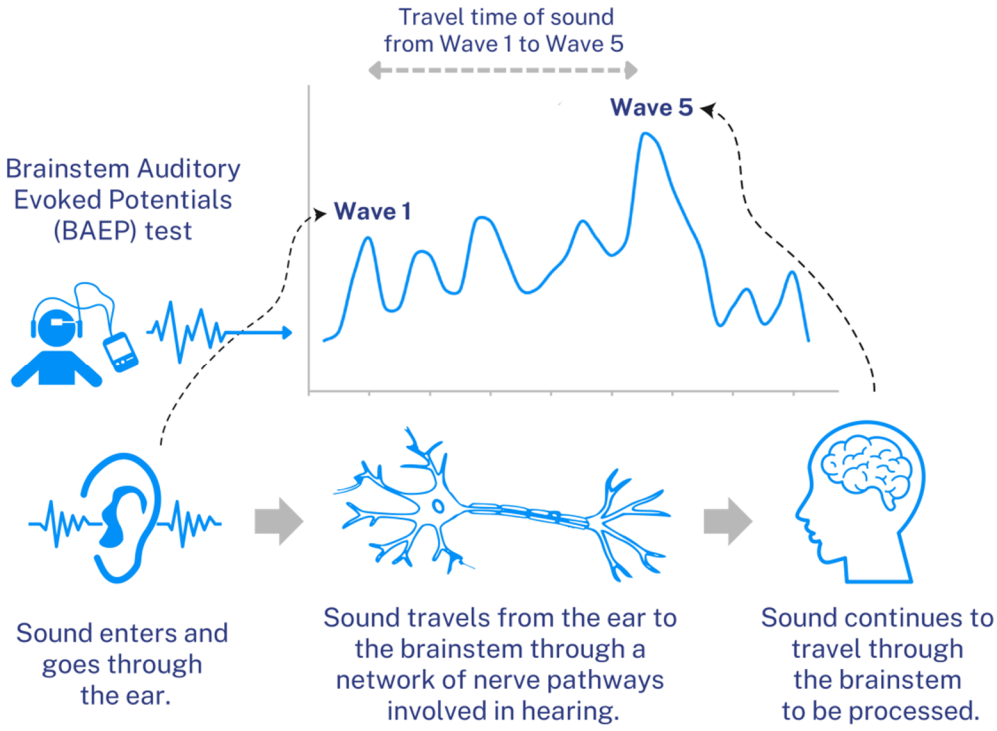
What were the results of the study?

Did ritlecitinib cause a change in the travel time of sound from the ear to the brainstem compared to placebo?

To answer this question, participants had a test called Brainstem Auditory Evoked Potentials (BAEP).

- The BAEP records the travel time of sounds as wavy lines (or waves) on a computer.
- The BAEP can tell study doctors about the time it takes for sound to travel from the ear (Wave 1) to the brainstem (Wave 5).

Figure 3. How sound travels from the ear to the brainstem (from Wave 1 to Wave 5 in the BAEP)



Participants had their left and right ears tested at 80 decibels. Decibels are a measure of how loud a sound is.

- First, participants had a BAEP test done at baseline. Baseline means at the start of the study. Then, participants had repeat BAEP tests during the study.
- The researchers measured the travel time of sound in the BAEP at baseline and at 9 months after treatment. They compared the results in the ritlecitinib group with those in the placebo group.

No. Researchers found no difference in the travel time of sound from the ear (Wave 1) to the brainstem (Wave 5) in the BAEP between participants who took ritlecitinib for 9 months and those who took placebo.

Did ritlecitinib cause a change in the amount and shape of nerve fibers in the skin compared to placebo?

To answer this question, study doctors took a small piece of skin sample from the participants' leg (skin biopsy).

- The study doctors used a microscope to look at the amount and shape of nerve fibers in the skin.
- The researchers assessed the amount and shape of nerve fibers at baseline and at 9 months after treatment. They compared the results in the ritlecitinib group with those in the placebo group.

No. Researchers found no difference in the amount and shape of nerve fibers in the skin between participants who took ritlecitinib for 9 months and those who took placebo.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

Among 71 participants who entered Part 1:

- 29 out of 36 participants (81%) in the ritlecitinib group had at least 1 medical problem.
- 22 out of 35 participants (63%) in the placebo group had at least 1 medical problem.

No medical problem led to participants leaving the study during Part 1.

Table 1 shows the most common medical problems (those reported by 3 or more participants in any group).

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during Part 1. It lists all medical problems reported by 3 or more participants in any group.
- The **2nd** column tells how many of the 36 participants taking ritlecitinib reported each medical problem. Next to this number is the percentage of the 36 participants taking ritlecitinib who reported the medical problem.
- The **3rd** column tells how many of the 35 participants taking placebo reported each medical problem. Next to this number is the percentage of the 35 participants taking placebo who reported the medical problem.
- Using these instructions, you can see that 3 out of the 36 participants (8%) taking ritlecitinib reported diarrhea. No participants taking placebo reported diarrhea.

Table 1. Most common medical problems reported in Part 1		
Medical Problem	**Ritlecitinib (36 Participants)**	**Placebo (35 Participants)**
Headache	4 out of 36 participants (11%)	1 out of 35 participants (3%)
Acne	4 out of 36 participants (11%)	0 out of 35 participants (0%)
Diarrhea	3 out of 36 participants (8%)	0 out of 35 participants (0%)
Vomiting	3 out of 36 participants (8%)	1 out of 35 participants (3%)
Coronavirus disease (COVID-19)	3 out of 36 participants (8%)	3 out of 35 participants (9%)
Dizziness	3 out of 36 participants (8%)	1 out of 35 participants (3%)
Feeling like one is about to vomit	1 out of 36 participants (3%)	3 out of 35 participants (9%)
Decreased feeling in the skin	1 out of 36 participants (3%)	3 out of 35 participants (9%)

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

Among 71 participants who entered Part 1:

- No participant in the ritlecitinib group had a serious medical problem.
- 1 participant in the placebo group had a serious medical problem, which was a break in the bone of the upper arm due to intense exercises.

No participant died during Part 1 of the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7981037**

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT04517864**
www.clinicaltrialsregister.eu	Use the study identifier **2020-001509-21**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help patients, and you helped
us to do that!