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 Studied:	Ritlecitinib (PF-06651600)
Protocol Number:	B7981031
Dates of Study:	02 March 2023 to 11 August 2023
Title of this Study:	A Study to Learn About the Study Medicine (Called Ritlecitinib) for the Potential Treatment of Severe Alopecia Areata in Children 6 to Less Than 12 Years of Age [An Interventional PK, PD, Phase 1, Open-Label Study to Investigate PK and PD of Multiple-Dose Ritlecitinib in Children 6 to Less Than 12 Years of Age With Severe Alopecia Areata]
Date of this Report:	05 February 2024

– Thank You –

If your child participated in this study, Pfizer, the Sponsor, would like to thank you and your child 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 (ALLO-pee-sha AIR-ee-ah-ta) is an autoimmune disease that causes hair loss. An autoimmune disease is a condition where a patient's immune system mistakenly attacks healthy parts of their body. Alopecia areata can affect adults and children across all ages, races, and sexes. Patients with alopecia areata may have lower self-esteem. They may also have problems with anxiety, depression, social relationships, and quality of life.

Patchy alopecia areata is the most common form of alopecia areata, when hair loss happens in one or more patches on the scalp or other places on the body that grow hair. Patchy alopecia areata may get worse and spread. Alopecia areata with loss of all scalp hair is known as alopecia totalis. Alopecia areata with loss of all scalp, face and body hair is known as alopecia universalis.

What is ritlecitinib?

Ritlecitinib (ri-tul-SIT-in-ib) (LITFULO™) is a medicine that is approved for the treatment of severe alopecia areata in people 12 years of age and older. At the time this study was done, ritlecitinib was an investigational treatment. An investigational treatment is one that is not approved for use outside of research studies.

Ritlecitinib is a small molecule medicine that is supplied as a capsule and taken by mouth. Small molecules can move into cells and interact with other molecules present inside a cell. Ritlecitinib is thought to work by blocking the activity of specific proteins in immune cells called "Janus Kinase 3" and the "TEC family kinases". These proteins act like on/off switches for the cells of the immune system. By turning off these switches,

the cells of the immune system produce fewer cytokines (a type of protein). This is expected to improve the symptoms of alopecia areata.

What was the purpose of this study?

At the time of this study, there were no approved systemic treatments (medicines that work throughout the whole body) for patients that are 6 to less than 12 years old with severe alopecia areata.

The purpose of this study was to measure blood levels of ritlecitinib after taking it for 7 days in patients 6 to less than 12 years old with severe alopecia areata.

By studying this, it can help researchers find the right amount of ritlecitinib to give patients in this age group for the treatment of alopecia areata.

Researchers wanted to know:

- **What was the amount of ritlecitinib in the blood after 7 days of taking 20 mg ritlecitinib once daily?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers gave ritlecitinib to a group of participants with alopecia areata to learn how it affected blood levels of ritlecitinib.

First, study doctors checked to make sure that participants met the requirements to be in the study. This is known as a “screening period”.

Participants that met the requirements to be in the study took 20 mg of ritlecitinib once daily for 7 consecutive days. Participants knew that they were taking ritlecitinib. This is known as an “open-label” study.

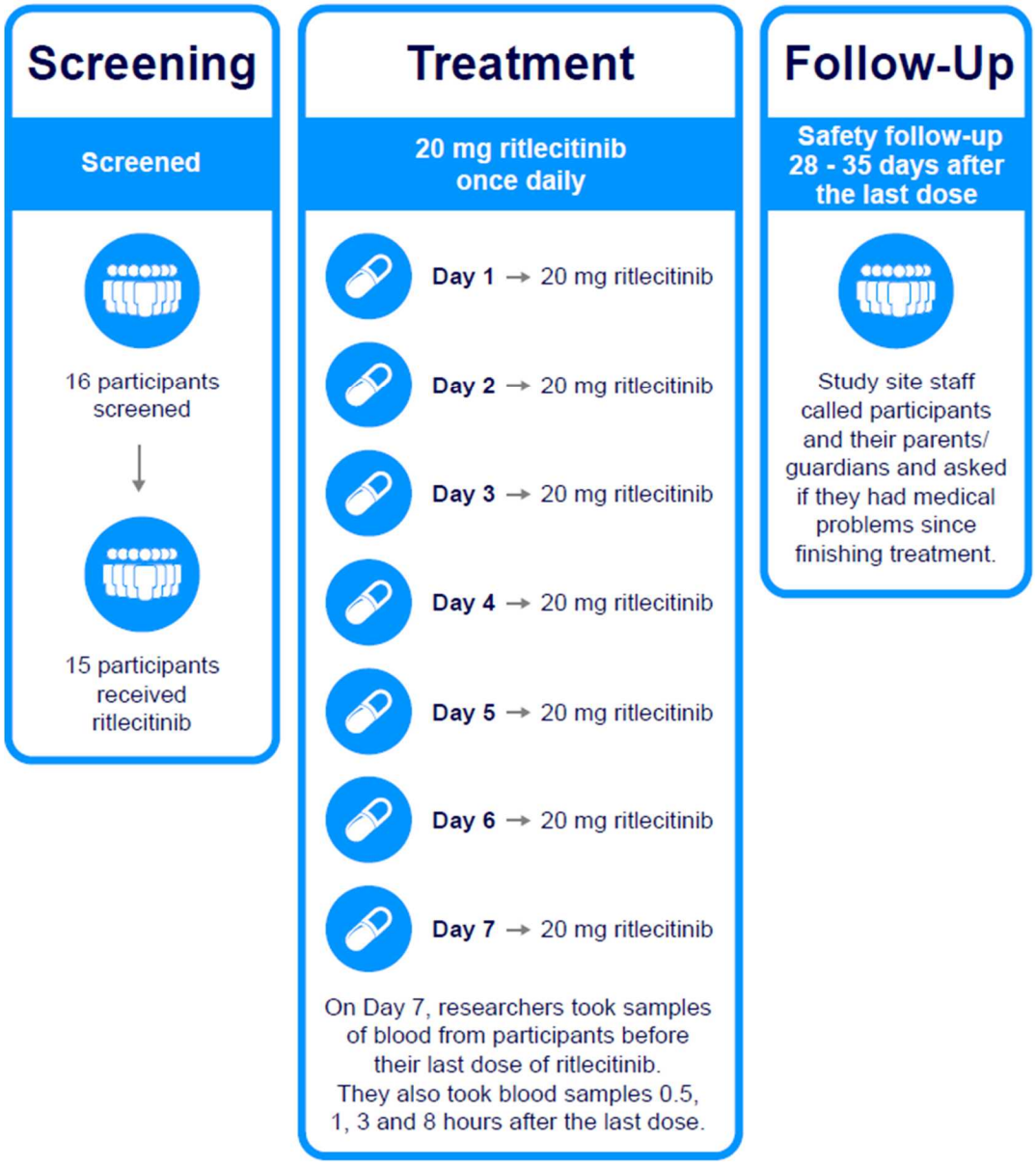
Participants and their parents/guardians were contacted by phone on days 2, 4, and 6 of treatment, and study site staff asked whether the participant had any medical problems since starting treatment.

On Day 7 (the last day of treatment), researchers took blood samples from participants before they took ritlecitinib and 0.5 hours, 1 hour, 3 hours, and 8 hours after taking ritlecitinib. This was done to measure the amount of ritlecitinib that was in the participants’ blood.

Participants and their parents/guardians were contacted by phone 28 to 35 days after the last dose of ritlecitinib to see whether the participant had any medical problems since finishing treatment.

A diagram showing what happened in this study is provided below in Figure 1.

Figure 1. Study Design



Where did this study take place?

This study was run at 6 locations in the United States.

When did this study take place?

It began on 02 March 2023 and ended on 11 August 2023.

Who participated in this study?

The study included participants aged 6 to less than 12 years with alopecia areata, with at least 50% of hair loss on their scalp and no signs of hair regrowth in the past 12 months. They also had to meet some other requirements.

- A total of 3 males participated
- A total of 12 females participated
- All participants were between the ages of 6 and less than 12 years old

Of the 15 participants who started the study, 14 finished the study. One participant did not finish the study because of a medical problem. Medical problems experienced by participants are described later in this report.

How long did the study last?

Study participants were in the study for up to 2 months. The entire study took about 5 months to complete.

When the study ended in August 2023, 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?

What was the amount of ritlecitinib in the blood after participants took 20 mg of ritlecitinib once daily for 7 days?

To answer this question, researchers measured the amount of ritlecitinib in the blood of participants on the last day of treatment (Day 7). They took blood samples from participants before they took the final dose of ritlecitinib

and then 0.5 hours, 1 hour, 3 hours and 8 hours after they took the final dose. Researchers could then estimate the amount of ritlecitinib was in the blood over 24 hours after taking the last dose.

The estimated amount of ritlecitinib in the blood during the 24 hours after participants took 20 mg ritlecitinib on Day 7 of treatment was 437.5 nanogram hours per milliliter, also called ng•hr/mL. The ng•hr/mL is a unit used to measure total amount of drug over time in the blood.

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 medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance), or medical problems could also be 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.

3 out of 15 (20.0%) participants in this study had at least 1 medical problem. A total of 1 participant left the study because of a medical problem of red itchy bumps on the skin (also called hives). All medical problems reported by participants are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists all medical problems that were reported during the study.
- The **2nd** column tells how many of the 15 participants taking the study medication reported each medical problem. Next to this number is the percentage of the 15 participants taking the study medication who reported the medical problem.
- Using these instructions, you can see that 1 out of the 15 (6.7%) participants taking the study medication reported feeling sick.

Table 1. All medical problems reported by study participants

Medical problem	Ritlecitinib 20 mg (15 Participants)
Feeling sick	1 out of 15 participants (6.7%)
Throwing up	1 out of 15 participants (6.7%)
Muscle pain	1 out of 15 participants (6.7%)
Red itchy bumps on the skin (hives)	1 out of 15 participants (6.7%)

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.

No participants had a serious medical problem. No participants died during the study.

Where can I learn more about this study?

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

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7981031**

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

www.clinicaltrials.gov	Use the study identifier **NCT05650333**
www.clinicaltrialsregister.eu	Use the study identifier **2023-000824-12**

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 your child 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!