A Pilot Study to Assess Safety and Biomarker Responses of Ritlecitinib (JAK3/TEC Inhibitor) in Cicatricial Alopecia

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STUDY INFORMATION:

Study Title: A Pilot Study to Assess Safety and Biomarker Responses of Ritlecitinib (JAK3/TEC Inhibitor) in Cicatricial Alopecia

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to evaluate the effectiveness and safety of Ritlecitinib which is the study drug and the effects of Ritlecitinib in skin and blood in persons with Cicatricial Alopecia (CA). CA, also known as scarring alopecia, is a type of alopecia in which hair follicles (which regulates hair growth) are irreversibly destroyed. CA leads to scarred areas, most commonly on the scalp, that cannot re-grow hair.

If you choose to take part, you will be asked to read and sign this consent form before any study tests are done. This study includes a screening period, a Treatment Period, an End of Treatment Visit, and a Follow-up Visit. Each period is explained in this consent form in the order that they will be completed. This study will involve physical examinations, visual assessments, laboratory tests, photographs of your scalp, eyebrows, eyelashes, and fingernails, skin biopsies, and hearing tests.

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Some of these lab samples may be stored. If you are eligible for this study, you will receive the study drug being tested, called Ritlecitinib for 48 weeks.

If you choose to take part, the main risks to you are upper respiratory tract infection, common cold (including inflammation of the tissue lining the sinuses, nasal passages and back of the throat), bronchitis (inflammation of the bronchial tubes that could lead to shortness of breath), headache, nausea, diarrhea, acne and decreased white blood cells, although the association with study drug is unclear.

You may benefit from taking part in this research. Some potential benefits are: The findings from this study may help to identify new therapies for this disease. You may also benefit from participation in this research if the study drug improves your condition, or improves your quality of life.

Instead of taking part in this research, you may decide to pursue other clinical trials or choose no treatment. There are currently no approved treatments for Cicatricial Alopecia.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have Cicatricial Alopecia and are at least 18 years old.

Your participation in this research study is expected to last 56 weeks. There are 15 in-clinic visits. You will be compensated for participating in the study.

There are 50 people expected to take part in this research study at Icahn School of Medicine at Mount Sinai.

Funds for conducting this research study are provided by Pfizer, Inc. The lead researcher/institution are being paid by Pfizer Inc. for the work done for this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

In addition to the visits listed, the study doctor may ask you to come in for extra visits if necessary to protect your well-being. A description of each test, procedure, or assessment is provided in this consent.

Screening Visit (should take between 1-2 hours):

- Demographic questions
- Medical history
- Physical exam
- Electrocardiogram (also called an ECG or EKG) This test measures the electrical activity of your heart. Sticky pads connected by wires to the ECG machine will be placed on your skin.
- Vital signs (blood pressure, heart rate)
- Height and weight
- Blood draw (about 6 teaspoons) and urine collection (about 3 teaspoons) including:
    - Safety tests
    - Tests for hepatitis B, hepatitis C, human immunodeficiency virus (HIV), and tuberculosis (TB) if applicable
    - Pregnancy test: this will be tested only if you are a female who can physically become pregnant
- Clinical Examination of your scalp, eyebrows, eyelashes and fingernails
- Audiological Evaluation (a hearing test that measures the range and sensitivity of your hearing)
- You will discuss with a member of the study team and agree on the type of birth control that you will use throughout the study and for 28 days after your last dose of tablets (only for individuals who are physically able to have children)

If you continue to qualify for the study, you will return for a Baseline visit. You will be given your study drug along with dosing instructions. All study participants will take Ritlecitinib 200 mg once daily for 8 weeks and 100 mg once daily for the rest of the study.

You will be asked to return to the study site for additional visits every 4 weeks through Week 52. Your Baseline visit will last approximately 1 ½ hours, Weeks 24 and 48 will take approximately 2 ¼ hours, and other visits will take about 45 minutes each.
The following procedures will be done at each visit:

- The research team will ask you about any updates to your medical history and medications you are taking
- A study doctor will examine your scalp, eyebrows, eyelashes and fingernails
- Your blood pressure and heart rate will be measured.

- Blood draw (about 11 tablespoons at the Baseline visit and 3 tablespoons at each other visit) and urine collection (about 3 teaspoons) including:
    - Safety tests (you will need to fast for 8 hours before your Baseline, Week 24 and Week 48 visits)
- If you are an individual of child bearing potential, a urine sample will be collected for a pregnancy test. This test must be negative to continue to qualify for this study.

The following procedures will only be performed at some visits as noted:

- You will be asked to fill out a short questionnaire about your overall health and quality of life called the Dermatology Life Quality Index (Baseline, Weeks 8, 16, 24, 32, 40, 48 and 52).
- You will be asked questions regarding past and current thoughts of suicide (Baseline, Weeks 8, 16, 24, 32, 40, and 48).
- You will have a blood sample drawn for:
    - specialized tests that look at biomarkers in your blood to see how the study drug works in your body, how your body responds to the study drug, and if certain biomarkers can predict how severe the disease may be (Baseline, Weeks 8, 24 and 48).
    - Pharmacokinetic (PK) tests, which evaluates how your body uses the study drug and how fast or slow the study drug moves through your body. A blood sample will be taken before you take your daily dose of tablets in the office at the Baseline, Week 4 and 20 visits. At Weeks 4 and 20 another blood sample will be collected at 30 minutes, 1 hour and 2 hours after taking your dose).
- Electrocardiogram (also called an ECG or EKG). This test measures the electrical activity of your heart. Sticky pads connected by wires to the ECG machine will be placed on your skin (Weeks 8, 16, 24, 32, 40 and 48).
- Audiological Evaluation. (Week 24 and Week 48).

Biopsies

- *You will undergo four-five punch biopsies (4.5 mm in size each) of your scalp during the study.* A biopsy is a tissue sample, in this case a small skin sample, from which a lot of information can be obtained. *4.5 mm is the equivalent of the eraser on a pencil head. Each will require 2-3 stitches that will be removed by the study doctor or study nurse 10-14 days later. At the Baseline visit, you will have 2 biopsies: one of these will be from your affected scalp skin, and the other from non-affected scalp skin.* You will have an additional punch biopsy of your affected scalp skin taken at Week 8, and one at Week 24, and another optional biopsy at week 48.. Before the biopsy is performed, the skin will be cleaned, then disinfected and locally anaesthetized (to numb the skin). Then a cookie-cutter-like instrument is pressed into your skin to remove a small piece of tissue. You will be instructed on how to care of the biopsy site. Photographs of your scalp, eyebrows/eyelashes and fingernails may be taken. The photo of your eyebrows/eyelashes will be close-up so that it will be difficult for anyone to identify you from the photos. These photographs may be used for publication in the future. All efforts will

be made to photograph areas that do not include the face or any other identifying markers (tattoos). If there are any views that show your entire face or any identifying markers, they will be blacked out in any publication. You cannot participate in the trial if you do not consent for photographs to be taken. These may be taken at Baseline and every 8 weeks thereafter and at Week 52.

The treatment period will conclude at week 48, and study participants will be asked to return for a follow up visit at week 52 (end of trial) for continued observation of scalp and hair changes. At that visit the research team will ask you about *any updates to your medical history and medications you are taking, you will be asked to complete a questionnaire about your overall health and quality of life, your scalp eyebrows, eyelashes and fingernails will be visually examined, photographs may be taken, and a blood sample will be collected for safety testing. Females of child bearing potential will be asked for a urine sample so that a pregnancy test can be performed.*

If you are discontinued or decide to discontinue your participation in this study, you will be asked to have most of the procedures and assessments stated above.

Because this research study involves the use of study drug, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

HIV/AIDS

To take part in this research study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study.

Pregnancy

If you can possibly get pregnant, a serum test for pregnancy will be done before you begin the study and a urine pregnancy test will be repeated at every visit.

You cannot be included in the study if you are or become pregnant, as the study drug could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study drug could harm your baby.

Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible, you should use effective birth control. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study and for one month after the research study ends. You should ask a doctor on the research team if you should continue birth control for longer than 30 days after your last dose. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, you could still become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time during the study, you must tell a person from the research team immediately. The team may stop the study drug and refer you/your partner to an obstetrician/gynecologist for follow-up.
Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens.

Semen/Sperm:

Drugs can be found in semen and alter sperm. Since you are taking part in a study using experimental drugs or treatments, it is recommended that 1) you use a condom, 2) you do not get a partner pregnant or expose them to semen, and 3) you do not donate semen. These recommendations apply both while you are taking the study drug, and for 3 months after you stop taking the study This is because levels of the study drug may be present in the sperm and/or semen even after you stop

taking the study drug. You are encouraged to tell your partner(s) and/or their doctor(s) that you are participating in this clinical trial.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your data and/or samples in the following way:

a) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial below:

I would like my data and/or samples stored with a link to my identity through the use of a code_____

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____ No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- While you are taking part in this study, you should not take part in another study without notifying the study doctor.
- You must follow the instructions you are given by the study doctor and study staff. If you do not follow the instructions, your visit may have to be rescheduled, or you may be discontinued from the study.
- Tell the study doctor or the study staff about all prescription and non-prescription medications, supplements, herbal preparations, or vaccines before you take them.
- Notify the study doctor or study staff if you move and provide your new address and contact information.
- Inform the study doctor of any changes to your skin while in the trial.
- Adhere to appropriate birth control methods as outlined in the Description of What's Involved section.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There may be costs to you for taking part in this study. Certain safety tests or assessments may uncover underlying diseases or problems that require medical attention.

If you agree to take part in this study, you will be paid $1050 for your time and effort if you complete all study visits. The research team will pay you $175 for visit 2; $50 for visits 3, 5, 6, 7, 9-13, and visit 15; and $125 for visits 4, 8, and 14. You will not be compensated for the screening visit. If you do not complete this study, for any reason, you will be paid for the study visits you do complete.

Payment will be given to you in the form of a check at the end of the study. It can take up to 8 weeks to prepare and give you a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as

applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

It is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include: improvement of your CA or a shorter CA flare.

POSSIBLE RISKS AND DISCOMFORTS:

Physical Risks:
In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).

There are risks to taking part in any research study. Side effects may occur. Some of those side effects can be treated. Some side effects may go away when you stop taking the study drug. Some side effects can be mild, but others may continue longer or become permanent. Some may be life-threatening or fatal.

As this study continues, the drug manufacturer may learn more information about the study drug. You will be given new information about this study in a timely manner. This way you can decide if you want to continue to take part in this study. You may be asked to read and sign a new consent form.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

Study drug Ritlecitinib Risks:

Ritlecitinib has been studied in healthy volunteers (in single doses up to 800 mg and multiple doses up to 400 mg daily for 14 days), study participants with rheumatoid arthritis (at the dose of 200 mg daily for 8 weeks), participants with alopecia areata (50 mg or 30 mg daily [with or without a starting dose of 200 mg daily for 4 weeks] for a total of 48 weeks), and participants with vitiligo (50 mg daily [with or without a starting dose of 200 mg or 100 mg daily for 4 weeks] or 30 mg daily for a total of 48 weeks). Participants with ulcerative colitis were also studied (a starting dose of 20 mg, 70 mg and 200 mg daily for 8 weeks, followed by 50 mg daily for 24 weeks).In those human studies, over 1600 people were exposed to Ritlecitinib, which was generally safe and well tolerated. There are also

ongoing studies of Ritlecitinib in study participants with ulcerative colitis, Crohn's disease, alopecia areata, and vitiligo.

The negative effects that were reported in more than 5% (1 in 20) of 715 participants with alopecia areata receiving Ritlecitinib in a 48-week study were: headache, infections of upper respiratory tract, acne, diarrhea, nausea, folliculitis (inflammation of the hair follicles), and urticaria (hives).

Certain viruses remain in the body and they may reactivate (wake up) and cause negative effects. In studies with Ritlecitinib or other similar medications, reactivation of the chicken pox virus (herpes zoster) has caused shingles (a skin condition with blisters, accompanied by burning or pain which may last after the rash clears), and reactivation of the herpes simplex virus has caused cold sores or fever blisters in the mouth or genital ulcers. The research team don't know if Ritlecitinib could lead to the reactivation of hepatitis viruses. You will not be allowed to participate in the study if your blood tests show that you have had hepatitis types B or C viruses. You will not be allowed to participate in the study if you have had more than one episode of shingles or if you have ever had even a single episode of shingles or herpes virus infection that spread inside your body or widely over your skin. During the study, call your study doctor right away if you think you may have shingles, ulcers in the genital area, or cold sores.

Ritlecitinib works by affecting your immune system. It can lower the ability of your body to fight infections, leading to more serious infections or infections that usually don't occur in people with a normal immune system. A serious infection (which can be caused by bacteria, fungi, or viruses) means that you may have to stay in the hospital for treatment of the infection and/or receive treatment through an injection. The serious infection may potentially be life-threatening. You may need to temporarily (until the infection has cleared) or permanently stop your study drug. Some people have had serious infections or unusual infections while taking Ritlecitinib or other similar medications. You will not be allowed to participate in the study if you have any kind of infection. After starting Ritlecitinib, call your study doctor right away if you have any symptoms of an infection. Symptoms of an infection could include fever, weight loss or excessive tiredness or other symptoms specific to the site of infection, such as a persistent cough. You will be discontinued from the study if you develop a serious infection. Ritlecitinib can make you more likely to get infections or make worse any infection that you may already have.

Ritlecitinib may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphomas (a type of blood cancer) and other cancers, including skin cancers, have been reported in patients taking medications that work in a similar way to Ritlecitinib. Cases of cancer (for example breast cancer) have been reported in clinical studies with Ritlecitinib. Most people with a history of cancer will not be eligible for this study, except for those who have had successfully treated skin cancers that were not the melanoma type and those who have had successfully treated local cancer of the cervix (the lower part of the uterus). Talk to your study doctor if you have had any type of cancer.

Your study doctor will perform blood tests before you start taking Ritlecitinib and while you take Ritlecitinib. Some changes in blood tests that have occurred in earlier studies with Ritlecitinib are described below. You will have these blood tests at study visits and you will be discontinued from the study if certain blood tests change to a level which would cause concern for your continued participation in the study.

- Decreases in lymphocyte counts. Lymphocytes are white blood cells that help the body fight off infections. If your lymphocytes are low, you might be more likely to get an infection.
- Changes in neutrophil counts. Neutrophils are white blood cells that help the body fight off infections. If your neutrophils are low, you might be more likely to get an infection.
- Decreases in platelet counts. Platelets are blood cells that help blood to clot. If your platelets are low, you might be more likely to bruise or bleed. Although bleeding or bruising related to low platelets has not been seen in previous studies with PF- 06651600, there is still a potential risk that this could happen.
- Changes in other laboratory tests, such as your blood cholesterol or hemoglobin (red blood cells) levels, may also be seen. Those tests and others will be checked on a regular basis through the study.

Occurrences of rash, acne, folliculitis (inflammation of the hair follicles) and urticaria (hives) have been observed in studies with Ritlecitinib. The majority of events were reported as mild. It is not known if Ritlecitinib causes these skin effects other than urticaria (hives), which appears to occur more often in people treated Ritlecitinib. **During the study, you should inform your study doctor if you notice any changes on your skin.** In some cases, your doctor may take a swab and/or skin biopsy (a small sample of skin that is cut and removed) to investigate a rash. Photographs of rashes may also be taken.

Medications that work in similar ways to Ritlecitinib (JAK inhibitors) may increase the risk of developing a blood clot in your legs (deep vein thrombosis) or lungs (pulmonary embolism). Cases of blood clots (including pulmonary embolism) have been reported in clinical studies with Ritlecitinib.

You should seek medical attention right away if you have any symptoms that could be due to a blood clot in your legs (such as pain in your leg, swelling in the leg, a feeling of warmth in the leg, red or darkened skin on the leg) or due to a blood clot in your lungs (symptoms may include sudden shortness of breath, pain in your chest, coughing up blood, lightheadedness, irregular heartbeat, excessive sweating, clammy or bluish skin).

Tell your study doctor as soon as possible if you are diagnosed with a blood clot in your body.

Studies have been conducted in animals to identify risks that may occur in people that are given Ritlecitinib. In studies with dogs, changes in the nervous system were seen after 9 months of taking

doses more than 7.4 times higher than the 50 mg clinical dose. After 7 months, at even higher doses (estimated to be 33 times above the 50 mg clinical dose), a few dogs had hearing loss. All the changes in the nervous system and hearing loss got better after stopping the drug. Because the dog findings (single species) occurred only at doses higher than will be used long-term in this study, it is unlikely that there are related human risks from Ritlecitinib at the doses used in this study. However, hearing will be tested in this study. If you develop symptoms that might be due to nervous system disease, you may be referred for additional evaluation by a doctor who specializes in diseases of the nervous system.

Adverse cardiovascular safety events (i.e., events involving the heart and blood vessels, including heart attacks and stroke) have been reported with tofacitinib, another JAK inhibitor, in patients with rheumatoid arthritis aged 50 years or older with at least one additional cardiovascular risk factor (e.g., cigarette smoking, high blood pressure). Inform your study doctor if you have had any type of heart or brain disease, such as a heart attack or a stroke. You should seek medical attention right away if you have any symptoms that could be due to a heart attack (such as pain or discomfort [lasting for more than a few minutes or that goes away and comes back] in your chest, jaw, neck, back, arms or shoulders, shortness of breath, cold sweat, clammy skin) or stroke (such as sudden numbness or weakness in one part or on one side of your body, sudden trouble speaking, sudden trouble seeing in one or both eyes, sudden loss of balance). Tell your study doctor as soon as possible if you are diagnosed with a heart attack or stroke.

There may be rare and unknown side effects with taking Ritlecitinib. Some of these side effects may be life threatening.

It is important that you report all side effects that you experience as soon as they occur, regardless of whether or not you believe they are caused by the study drug.

If you do not understand the risks described above, please ask the study doctor or study staff to explain them to you.

Risk of Allergic or Hypersensitivity Reaction

There is a chance that you may experience a local or generalized allergic reaction (also known as hypersensitivity reactions) to the study drug. One kind of allergic reaction can happen immediately (within minutes or hours) after taking study drug. This is called anaphylaxis. Symptoms of immediate allergic reaction may include skin flushing, rash or hives, sneezing, runny nose, difficulty breathing, wheezing, sudden cough, a sense of choking, sudden change in blood pressure (causing dizziness or lightheadedness), swelling around the mouth, throat, or eyes, fast pulse or sweating, abdominal cramps, diarrhea, passing out, and a sense that something bad is going to happen. The severity of this type of immediate reaction ranges from mild to severe. A mild reaction may progress to a more severe one, so you should contact the study personnel if you experience any new symptoms occurring within a couple of hours after study drug injection.

A severe allergic reaction requires immediate medical treatment and could result in permanent disability or death if not treated promptly. If you believe you are having a severe allergic reaction, you should immediately seek emergency medical treatment and alert the study doctor and study staff as soon as possible.

Pregnancy-related risks/Use of birth control

At this time, the effects of Ritlecitinib on fertility, and pregnancy in humans, and effects on the fetus or a nursing child are not known.. Due to the investigational nature of Ritlecitinib, it should not be administered to pregnant or breastfeeding individuals or individuals of childbearing potential who are unwilling or unable to use contraception as defined in the study protocol. If you are currently pregnant, plan to become pregnant or are breastfeeding a child, you should not join this study. If you think you are pregnant, tell the study doctor immediately. Pregnancy and non-adherence to birth control will be a reason to stop taking the study drug.

If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major for the pregnancy. You should not become pregnant or get a woman pregnant while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document

Risk of loss of private information: this risk always exists, but there are procedures in place to minimize the risk.

Biopsy Risks: The local anesthetic injected before the skin biopsies may induce a brief burning sensation. While rare, you could have an allergic reaction to the anesthetic. Symptoms of an allergic reaction include hives or swelling of the face, lips, tongue, or throat, which may cause difficulty in breathing or swallowing. This could become life-threatening if not treated promptly. Please advise the study doctor if you have had a previous reaction to any local anesthetics.

Serious side effects from a skin biopsy are rare. The study doctor or another qualified person will use a numbing medicine (anesthetic) injection to eliminate any pain during the biopsy procedure. If you feel pain, please tell the study doctor so he or she can inject more anesthetic to make the procedure painless. The biopsy area might feel uncomfortable after the skin sample is taken. A small scar (approximately 4.5 mm) will form once the area has healed. Occasionally, some people who do not heal well may have a thick and itchy scar that is larger than the skin biopsy site (this is called hypertrophic scar or keloid). Please let the study doctor know if you have ever developed a bad scar after a skin cut. There is also a small chance that the biopsy site may become infected which could result in pain, redness, or swelling of the area. There is also a small chance that a superficial nerve (a nerve that is responsible for the sense of touch) might be cut during the procedure. If this happens, the skin around the biopsy site may become insensitive to touch or pain. Discomfort or pain is sometimes present for a few weeks after a skin biopsy.

ECG Risks: The sticky pads placed on your skin may cause some redness or itching when the pads are removed.

The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. You should not become pregnant or get someone pregnant while you take part in this study. Please read the acceptable methods of birth control found under the Description of What Is Involved section of this document.

Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

There are currently no FDA-approved treatments for cicatricial alopecia. Commonly used treatments include corticosteroids, either topical or systemic as an injection to the affected area. Although steroids can help with inflammation, their long-term use is not often recommended due to side effects such as skin thinning (topical) and high blood pressure (systemic).

The study doctor will discuss other options and their potential risks and benefits with you before you decide whether you will take part in this study. You may also discuss your options with your regular doctor.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

The Centers for Medicare and Medicaid Services (CMS) is the government agency that oversees Medicare and Medicaid. Funding agencies who make payments for injuries related to studies must report payments to CMS. In order to do this, the funder must have certain information about you, such as your name, date of birth, Social Security Number, Medicare or Medicaid ID numbers, date of injury, and description of injury. The funding agency is only allowed to use this information to report payments related to the injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. For your safety, once you stop the study drug you will be asked to complete the End of Treatment Visit and Follow-Up Visit tests (as described in the description section of this form).

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide to stop being in the research study, the following may occur: any improvements in your CA may be lost or your CA may worsen.

If you stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been

shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-3288.
If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The company sponsoring this research study makes the drug or device being tested and has a financial interest that could be affected by the outcome of this research study.

Dr. Emma Guttman (the lead researcher this study) and Dr. Benjamin Ungar (a researcher in this study) are paid consultants for Pfizer, sponsor of this study and developer of the study drug ritlecitinib. In addition, Dr. Guttman and Dr. Ungar are paid consultants for other companies that research and develop treatments for dermatological diseases, such as alopecia.

If you have questions regarding paid relationships that your physician/researcher may have with industry, you are encouraged to talk with your physician/researcher, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail social security number, or photographic images
The researchers will also get information from your medical record (you will be asked to sign a release so that your primary care doctor or dermatologist can send us your medical records).

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in

this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Mount Sinai laboratories who will be performing laboratory analysis for our research center.
- Our collaborator on this study, Pfizer, Inc., and their representatives or business partners, including those in other countries. Any reference to the collaborator includes their research partners and service provider including companies belonging to the collaborator, and any person or company that acquires them or the rights to the study drug (Ritlecitinib). The research team will send study data and results to Pfizer. Information sent to Pfizer will not include information that directly identifies you (such as your name and Social Security number) and will be coded with a participant identification number.
  In the future, Pfizer and their representatives, may continue to use coded health information that is collected as part of this study. Pfizer may share information from the study with regulatory agencies
- The IRB overseeing this study: The Program for the Protection of Human Subjects
- The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers.
Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION: ○ N/A

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time