copernicus group independent review board

Approved: 28Aug2015

INFORMED CONSENT FORM PART A AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE PERSONAL MEDICAL INFORMATION AND RECORDS

Study Title:	An Open-Label (Part A) and a Double-Blind, Randomized, Placebo-Controlled (Part B) Study, With an Open-Label Extension, of INCB018424 Phosphate Cream Applied Topically to Subjects With Alopecia Areata
Protocol No.:	INCB 18424-204
Study Sponsor:	Incyte Corporation
Study Doctor:	**Suzanne Bruce MD**

Research Site Address(es):

Suzanne Bruce and Associates PA The Center for Skin Research
23510 Kingsland Blvd Ste 300
Katy TX 77494

Daytime Phone:	713-985-0210
24-Hour Phone:	713-503-9467

INFORMED CONSENT

You are invited to join voluntarily in a clinical research study to find out if the drug INCB018424 Phosphate Cream (Study Drug) is safe and has beneficial effects in people who have alopecia areata.

Before you agree to join this study, you need to know the risks and benefits so you can make an informed decision. This is known as "informed consent."

This consent form tells you about the study that you may wish to join. Please read the information carefully and discuss it with anyone you want. This may include a friend or a relative. If you have questions please ask the study doctor or study team to answer them.

Once you know about the study and the tests that will be done, you will be asked to sign this form to join this study. Your decision to take part in this study is voluntary. That means you are under no obligation to join the study, and refusal to join will not affect your medical care. You are also free to leave the study at any time for any reason without affecting your medical care. If you choose not to join in this study, you can discuss regular medical care with the study doctor.

INFORMATION ABOUT THE STUDY DRUG AND THE STUDY

INCB018424 Phosphate Cream is an investigational drug that is being developed by Incyte Corporation (the sponsor of the research study) for topical (applied to the skin) use in the treatment of patients with alopecia areata (AA, a disorder where a person will have partial or complete hair loss on their scalp). "Investigational" means that the drug has not been approved by the U.S. Food and Drug Administration (FDA) for the condition for which it is being studied here.

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

PURPOSE

The purposes of this research study are:

- To evaluate how safe, how it is tolerated, how effective, and the possible side effects when the INCB018424 cream (the "Study Drug") is applied to the scalp twice daily for the treatment of alopecia areata, compared to a matching placebo cream (inactive, non-medicated cream).
- To examine how the Study Drug works and how long it stays in your body.
- To evaluate the effect of INCB018424 on the scalp.

ABOUT THIS RESEARCH STUDY

The study is divided into two parts. Part A is an open-label design (you, your study doctor, and the sponsor will know which treatment you are receiving) and Part B is a double-blind, randomized, and placebo-controlled design.

In Part A, approximately 10 subjects will be treated with the Study Drug, INCB018424 1.5% cream, twice a day for 24 weeks. Qualified subjects in Part A will be offered an additional 24 weeks of open-label treatment.

This consent form explains participation in Part A, which is the open-label portion of the study. This means you will be receiving INCB018424 1.5% cream in the study. Part A and Part B may be ongoing at the same time.

Your participation in the study may last up to 48 weeks. All subjects will have 6 visits and two follow up visits. Part A subjects that continue into the extension part of the study will have 4 additional visits.

The Study Drug will be applied to the scalp as a thin film and gently rubbed into the surface of the scalp in the morning and in the evening at least 1 hour before bedtime. The treatment area must be washed with a mild soap and water and patted dry prior to application of the Study Drug. If used, occlusive camouflage (wearing a head covering) or other contact should be avoided for at least 1 hour after an application.

STUDY PROCEDURES: PART A

Screening Visit (1-28 days prior to starting your first dose of study medication)

When you come in for your screening visit, you will undergo the following procedures:

- You will be asked if you have any questions about this study before any screening tests or other procedures are conducted.
- The study team will ask you some questions to see if you qualify for the study.
- Height and body weight will be measured.
- Medical history and medication history will be obtained.
- You will have a comprehensive physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Collection of a urine sample for urinalysis.
- Electrocardiogram (ECG, electrical tracing to measure your heart activity and health).
- The study doctor will assess your degree of hair loss using an alopecia assessment or Severity of Alopecia Tool Scoring System (SALT Scoring System).
- The study team will ask you about any changes in your health.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

- Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
- Hematology: measures the different kinds of red and white blood cells in your body. About 2 teaspoons of blood will be taken for this test.
- Serology: a test to look for Hepatitis B and C. About 2 teaspoons of blood will be taken for this test. The study doctor or study team will tell you if the results of the hepatitis tests are positive. The results of these tests must be negative in order for you to be in the study. If required by state or national law, the study doctor or study team may report a positive test result to the local health department.
- Follicle Stimulating Hormone (FSH) test: women who report amenorrhea (the absence of menstruation) to verify hormonal menopause.
- Serum pregnancy test: required for women of child bearing potential only. The study doctor or study team will tell you if the test results are positive. Women who are pregnant cannot participate in this study. About 1 teaspoon of blood will be taken for this test.

You may be asked to repeat screening which would mean you would undergo more examinations, medicine and/or tests if the study doctor thinks they are necessary in order to ensure your safety and health. S/he will discuss any additions with you.

Visit 1: Day 1

- The study team will ask you some questions to be sure you still qualify for the study.
- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical examination.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

  - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
  - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- You will have your Study Drug administered in the clinic.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 2: Week 4

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical examination.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
    - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
    - Pharmacokinetics sampling to examine how long the Study Drug stays in your body. About 1 teaspoon of blood will be taken for this test. You will have samples collected before you apply INCB018424 Phosphate Cream, 1 hour, 2 hours and 4 hours after you have applied the cream.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- You will have your Study Drug administered in the clinic.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 3: Week 8

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical examination.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

- Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
- Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only
- The study doctor will assess your degree of hair loss using the SALT Scoring System
- The study doctor will assess for any hair regrowth
- Your used and unused Study Drug tubes and diary will be collected
- You will have your Study Drug administered in the clinic
- You will be given enough Study Drug to last you until your next visit
- You will be given a diary to record your use of the Study Drug.

Visit 4: Week 12

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical examination.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

  - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
  - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
  - Pharmacokinetics sampling to examine how long the Study Drug stays in your body. About 1 teaspoon of blood will be taken for this test. You will have samples collected before you apply INCB018424 Phosphate Cream, 1 hour, 2 hours and 4 hours after you have applied the cream.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- You will have your Study Drug administered in the clinic.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 5: Week 18

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical examination.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
    - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- You will have your Study Drug administered in the clinic.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 6: Week 24 (End of Treatment)

Please note, if continuing on to the extension part of the study, procedures are described in the Open-Label Extension of Part A section of this informed consent. Visit 6 and both follow up visits as described in this section will not be completed.

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a comprehensive physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.

  - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
  - Pharmacokinetics sampling to examine how long the Study Drug stays in your body. About 1 teaspoon of blood will be taken for this test. You will have samples collected before you apply INCB018424 Phosphate Cream, 1 hour, 2 hours and 4 hours after you have applied the cream.

- Collection of a urine sample for urinalysis.
- If required, you will have a urine pregnancy test completed: required for women of child bearing potential only.
- Electrocardiogram (ECG, electrical tracing to measure your heart activity and health).
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

<u>One Month Follow-up</u>

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.

<u>Three Month Follow Up</u>

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

- Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
- Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

STUDY PROCEDURES: OPEN-LABEL EXTENSION OF PART A

Visit 6: Week 24

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a comprehensive physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

  - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
  - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
  - Pharmacokinetics sampling to examine how long the Study Drug stays in your body. About 1 teaspoon of blood will be taken for this test. You will have samples collected before you apply INCB018424 Phosphate Cream, 1 hour, 2 hours and 4 hours after you have applied the cream.

- Collection of a urine sample for urinalysis.
- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- Electrocardiogram (ECG, electrical tracing to measure your heart activity and health).
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.

- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.
- You will have your Study Drug administered in the clinic.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 7: Week 30

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
    - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- You will have your Study Drug administered in the clinic.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 8: Week 36

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.

- Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.
- You will have your Study Drug administered in the clinic.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 9: Week 42

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:

  - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test
  - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test

- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- You will have your Study Drug administered in the clinic.
- You will be given enough Study Drug to last you until your next visit.
- You will be given a diary to record your use of the Study Drug.

Visit 10: Week 48

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a comprehensive physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
    - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
    - Pharmacokinetics sampling to examine how long the Study Drug stays in your body. About 1 teaspoon of blood will be taken for this test. You will have samples collected before you apply INCB018424 Phosphate Cream, 1 hour, 2 hours and 4 hours after you have applied the cream.
- Collection of a urine sample for urinalysis.
- If required, you will have a urine pregnancy test completed: required for women of child bearing potential only.
- Electrocardiogram (ECG, electrical tracing to measure your heart activity and health).
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Your used and unused Study Drug tubes and diary will be collected.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

One Month Follow-up

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- If required, you will have a urine pregnancy test completed: required for women of child bearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.

Three Month Follow-up

- The study team will ask you about any changes in your health.
- The study team will ask you about the medications that you are taking now and if there have been any changes.
- You will have a targeted physical exam completed.
- Your vital signs (blood pressure, heart rate, breathing rate and body temperature) will be measured.
- Blood samples will be collected for laboratory tests to monitor your health, including the following:
    - Serum Chemistry: measures the health of your liver, kidneys, heart, and other organs. About 2 teaspoons of blood will be taken for this test.
    - Hematology: measures the different kinds of cells in your blood. About 2 teaspoons of blood will be taken for this test.
- If required, you will have a urine pregnancy test completed: required for women of childbearing potential only.
- The study doctor will assess your degree of hair loss using the SALT Scoring System.
- The study doctor will assess for any hair regrowth.
- Photographs will be taken of your scalp. Any identifiable features (such as eyes, mouth, tattoos) will be masked so that nobody can identify you in the photographs. You cannot be in this study if you do not want to have your photographs taken.

RISKS AND INCONVENIENCES

While participating in this study, you are at risk for side effects. Risks are possible side effects of the study drug, or another medicine, coming from study procedures such as drawing blood for laboratory tests. These side effects will vary from person to person. Commonly occurring, as well as rare but serious side effects that have been reported in other clinical studies with the study drug are listed in this form. You should discuss these with the study doctor as well as ask about side effects that may not be listed in the form. Some side effects go away shortly after taking the study drug is stopped, but in some cases side effects may be serious, long-lasting, and/or permanent, and may even cause death.

INCB018424 Phosphate cream has been evaluated topically in over 200 subjects in 3 clinical studies with dosing of 1 to 3 months in duration.

Adverse events possibly related to the Study Drug include:

- stinging, itching, irritation, pain, dryness, peeling and/or redness at the application site.

There may be risks involved that we do not know about yet.

If you experience any of the described symptoms or have any other problems, you must immediately tell the appropriate study team member or the study doctor.

Some drugs and substances might result in increased blood levels of INCB18424, therefore, you should always discuss the use of any drugs or substances (over-the-counter, prescription or herbal) with your study doctor while you are participating in this study.

There may be a risk of skin reaction to the combined exposure of INCB018424 and sunlight. You should avoid excessive exposure to either natural or artificial sunlight (including tanning booths and sun lamps), and, when outdoors, should wear loose-fitting clothing that protects the treated area from the sun.

With all medicines or procedures, there may be risks that we do not know about. You will be provided in a timely manner with any new information that may affect your willingness to participate in this study.

During this study, you should not change other treatments or medications you are currently receiving, except as directed by your study doctor, or if in an emergency as directed by your study doctor.

Side Effects from Study Procedures

Possible side effects from blood draws are fainting, bruising, soreness, tenderness at the needle site, and, on rare occasions, infection. The total amount of blood that will be drawn over the course of this study is approximately 5 ounces (133 mL). For comparison, the amount a person typically gives for a blood donation is 16 ounces (480 mL). Due to the amount of blood that we will take during this study, you should not give blood for at least 30 days after the study is over.

Possible side effects from the patches that are put on your skin when the ECG is performed may be a rash or minor irritation of the skin.

Risks of Pregnancy or Fathering a Child

The risks to an unborn human fetus or a nursing child from INCB018424 Phosphate Cream are not known. Women who are pregnant or nursing a child may not participate in this study.

You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant or father a child during the study. If there is any possibility that you may become pregnant or father a child during the study, the study doctor will discuss appropriate birth control measures with you. If you are female and suspect that you have become pregnant during the study, you must notify the study doctor immediately, and you have to stop study treatment immediately. You will not be able to continue in the study if you become pregnant. Your pregnancy will be followed to outcome. The study doctor will ask to follow the heath of your baby until the first well-baby visit.

If you father a child during your participation in the study, you must notify the study doctor immediately. If your partner becomes pregnant, your study doctor will ask to medically follow the pregnancy until delivery to monitor your partner's and your child's safety.

BENEFITS OF TREATMENT

You may or may not receive direct benefit from being in this study. However, taking part may help alopecia patients get better care in the future.

TREATMENT OPTIONS

This is a research study and does not constitute treatment or therapy. There may be other treatment options that are available to you, including receiving other therapies such as the use of a topical steroid cream. You should speak to your doctor about all of your treatment options prior to deciding to participate in this study.

NOTES REGARDING YOUR PARTICIPATION IN THIS STUDY

1. Your participation in this study is voluntary. You will be starting the study out of your own free will, without any kind of pressure, and you may quit the study any time you wish. Your decision to stop participating in the study will have no penalty or loss of benefits to which you are otherwise entitled.
2. The duration of your participation in this study will be approximately 24 or 48 weeks during which time you may not participate in other research studies.
3. You may be asked to take more examinations, medicine and/or tests if the study doctor thinks they are necessary in order to ensure your safety and health. If you have problems, you will get medical attention.
4. You may be withdrawn from the study by the study doctor, FDA, Copernicus Group Independent Review Board (CGIRB), and/or sponsor of the study without your consent, if: (1) the study doctor feels it is not in your best interest to continue in the study, (2) you fail to follow the study doctor's instructions, (3) you experience an adverse reaction that requires other medical treatment, (4) you become pregnant, or (5) the sponsor or the FDA or other regulatory authority stops the entire study for any reason.
5. If you do not complete the study, you will be asked to undergo all of the assessment and evaluations noted in the End of treatment visit schedule. You may also be asked to provide some additional follow-up information to your study doctor.
6. It is your responsibility during this study to follow the direction of the study doctor, show up to the protocol specific visits, take the Study Drug as prescribed and notify the study team of any side effects (adverse events) regardless of the relationship to the Study Drug.

COSTS AND COMPENSATION FOR PARTICIPATION IN THIS STUDY

During your participation in this study, all examinations related to the study, the study drug and any other materials will be provided at no cost to you.

You will be paid up to $50.00 per visit to reimburse you for your travel expenses as a direct result of participating in this study. If you do not complete the study, you will be paid for the visits that you have completed.

You will have the option of receiving compensation either at the end of each visit or at the end of your study participation

COMPENSATION FOR INJURY RESULTING FROM THE STUDY

It is important that you follow carefully all the instructions and the schedule visits given by the study doctor and his staff regarding this study.

If you become ill or are physically injured as a result of participation in this study, please contact the study doctor right away; (s)he will treat you or refer you for treatment.

The reasonable costs of such treatment beyond that provided by your insurance will be covered by the sponsor, Incyte Corporation. The sponsor will provide payment for medical expenses for injuries:

- if you received reasonable medical care
- if you followed instructions and the schedule visit
- if the injury is related to the study drug or to properly performed study procedures that are not part of your usual medical care
- that are not the result of the natural course of any underlying disease and/or pre-existing disease process present prior to the proper administration of the Study Drug or Best Available Therapy.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, the sponsor or the involved institutions from their legal and professional responsibilities.

STUDY FUNDING

This research is being funded by the sponsor, Incyte Corporation. The sponsor has signed a contract with Suzanne Bruce and Associates PA The Center for Skin Research under the direction of Suzanne Bruce MD to conduct this research study as outlined in the study protocol.

CONFIDENTIALITY

While participating in this study, the study doctor will replace your name with a special code that identifies you. It may include your initials, date of birth, and study visit dates. This code, along with your study information, will be used by the sponsor and its/their representatives, for the study purposes mentioned above and to determine whether the Study Drug is safe and effective. The sponsor may share your coded information, as necessary, with the people and organizations listed above, Copernicus Group Independent Review Board (CGIRB), regulatory agencies such as the US Food & Drug Administration (FDA), and other health authorities and regulatory bodies in other countries such as the European Medicines Agency.

If information about this study is published, you will not be identified.

There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible.

CONTACTS
If you have questions about the research, please contact the study site. In the event of a research-related injury, please contact the study doctor.

Study Doctor:	**Suzanne Bruce MD**
Daytime Phone:	713-985-0210
24-Hour Phone:	713-503-9467

You should contact the study doctor first if you have questions, complaints, or concerns about the study.

Please call Copernicus Group IRB at 1-888-303-2224 if:

- You want to talk to someone other than the study doctor or study staff.
- You have a hard time reaching the study doctor or study staff.
- You have questions about your rights as a research subject.

Please visit the Copernicus Group IRB website www.cgirb.com for more information about research studies and the role of a research subject.

Subject Statement of Consent

An Open-Label (Part A) and a Double-Blind, Randomized, Placebo-Controlled (Part B) Study, With an Open-Label Extension, of INCB018424 Phosphate Cream Applied Topically to Subjects With Alopecia Areata

I am signing this form freely and am not being forced. I understand that by signing this form, I do not lose any rights to which I am otherwise entitled.

I hereby state that I have the legal capacity to consent for myself and that no guardian has been appointed for me. I have read and understand the consent form, and all of my questions have been answered. I understand that I will receive a signed and dated copy of this form. I agree to cooperate with all the medical personnel and to take the medicines and treatments as directed.

_____ _____

Subject's Signature Date

_____

Printed Name of Subject

The information about the study was described to the subject in language he/she understood.

_____ _____

Person Obtaining Consent Signature Date

_____

Printed Name of Person Obtaining Consent

Statement of the Witness (when applicable*)
The information in the consent form was accurately explained to, and appeared to be understood by the subject. Informed consent was freely given.

_____ _____

Signature of Impartial Witness Date

_____

Printed Name of Impartial Witness

*Impartial Witness: If the subject cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your regular doctor or your specialist of your participation in this study.

☐ Yes, I want the study doctor to inform my regular doctor/specialist of my participation in this study.

☐ No, I do not want the study doctor to inform my regular doctor/specialist of my participation in this study.

☐ I do not have a regular doctor/specialist.

☐ The study doctor is my regular doctor/specialist.

AUTHORIZATION TO COLLECT, USE AND DISCLOSE PERSONAL MEDICAL INFORMATION AND RECORDS

This section sets forth the people and organizations who you permit access to and use of your coded information, your medical records and your identifiable health information ("Study Information").

Your name will be available only to the following people or organization: the study doctor and study team; authorized representatives of the study doctor; Copernicus Group Independent Review Board (CGIRB), health authority inspectors, such as the US Food & Drug Administration (FDA) and the European Medicines Agency; the sponsor, its affiliates and business collaborators, people working with sponsor and its representatives including study monitors and auditors; and authorized clinical research organization representatives. The above mentioned people and organizations will use your Study Information to check that the study is conducted correctly and to ensure the accuracy of the study information. These people and organizations are all obligated to maintain confidentiality by the nature of their work, or are bound by confidentiality agreements. With your permission, the study doctor may contact your personal physician to collect additional medical information and your past medical history.

By signing this document, you are giving permission to the study doctor to share your study information with the people and organizations listed above. However, once your study information is shared as authorized, it may no longer be protected by Federal law and may be re-disclosed without your permission.

Study information, your study code, and samples collected as part of this study will be included in the sponsor's secure electronic clinical study systems. These systems may be managed and monitored by companies who work with the sponsor.

The people, companies, and agencies listed above that have access to your information may be located in: the United States; Switzerland; and other countries around the world. Therefore, your medical information (including study photographs) will be transferred to these countries.

You should be aware that some countries may not offer the same level of privacy protection as you are used to in the US. However, the sponsor will keep any information it receives as confidential as required by applicable local law. The sponsor has also entered into agreements with third parties working with the sponsor to ensure the confidentiality of your data and samples.

Your participation in this study is voluntary and you may withdraw your authorization at any time and without any reason by sending written notice to the study doctor at the address listed on the first page of this form. If you do so, your participation in the study will end and the study team will stop collecting information from you unless you have a side effect related to the study. You will have the right to request that your samples be destroyed. However, the sponsor will continue to retain and use any research results that have already been collected. If you wish to leave the study inform your study doctor in writing.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

If you decide not to sign this Authorization, you will not be able to participate in the study. This Authorization is valid unless and until you withdraw it in writing.

You have the right to review your Study Information and medical records and request changes to the study information if it is not correct. However, please note that during the study, access to study information may be limited if it weakens the integrity of the research. You may have access to the study information held by the study doctor at the end of the study.

If you have any questions about the collection and use of information about you, or would like to exercise rights that you may have regarding this information, you should ask your study doctor.

AUTHORIZATION

By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

Printed Name of Subject

Subject's Signature **Date**

Statement of the Witness

The information in the authorization was accurately explained to, and appeared to be understood by the subject. Informed consent was freely given.

Printed Name of Impartial Witness

Signature of Impartial Witness **Date**

*Impartial Witness: If the subject cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.