INFORMATION AND CONSENT FORM

Study Title: Open-Label Study of ATI-502 Topical Solution for the Treatment of Alopecia Areata (AA), Alopecia Universalis (AU) and Alopecia Totalis (AT)

Study #: <<protocol number>>

Sponsor: <<sponsor>>

Study Doctor: <<investigator>>
<<firm name>>
<<street address>>, <<city>>, <<state>> <<zip>>

Telephone Number: <<000-000-0000>>

After Office Hours: <<000-000-0000>>

The study doctor wants to know if you would like to be part of a research study.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

WHAT IS THIS STUDY ABOUT?

You are currently participating in the ATI-501-AUAT-201 study to see if ATI-501 Oral Suspension can help regrow hair in people with stable alopecia areata (AA), alopecia universalis (AU), or alopecia totalis (AT). You have now finished the portion of the study where you are taking ATI-501 Oral Suspension or Placebo twice daily and the researchers would like to provide you with the option to continue experimental treatment with a topical solution.

Researchers want to find out more about an investigational drug called ATI-502 Topical Solution. An “investigational” drug is a drug that is being tested as a potential treatment and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

Currently, there is no proven treatment for AA or its more severe forms AU and AT. Increases in the understanding of what causes AA has led to the development of the new drug ATI-502, which may help to stop the body from attacking the hair follicles, which causes hair to stop growing and fall out.

The purpose of this study is to see whether ATI-502 Topical Solution (0.46%) is safe and well-tolerated when applied to the scalp of those with AA, AU and AT. Additionally, researchers want to find out if ATI-502 Topical Solution can maintain or improve hair regrowth in people who completed 24 weeks of treatment with ATI-501 Oral Suspension or Placebo Suspension.

It is planned that about 80 people with stable AA, AU, or AT will be in this study.

Be aware that this form refers to ATI-502 Topical Solution (0.46%) as “study drug”.

HOW DOES ATI-502 TOPICAL SOLUTION WORK?

ATI-502 Topical Solution is an investigational drug in a Topical Solution that is designed to allow hair growth to occur again. ATI-502 Topical Solution has been used in several small studies in people with alopecia areata, but those studies are still ongoing and it is not yet known if ATI-502 will work.

IS THERE ANYTHING ELSE I CAN DO FOR MY ALOPECIA AREATA, ALOPECIA TOTALIS OR ALOPECIA UNIVERSALIS?

You do not have to be in this study to get help for your alopecia areata. Some other things you may be able to do are:

- Corticosteroids (anti-inflammatory medications), either topically applied or injected into your scalp,
- Immunosuppressive treatments (drugs that suppress your immune system) such as:
  - cyclosporine, methotrexate, or etanercept
- Phototherapy (a treatment that uses ultraviolet light) such as:
  - phototherapy with psoralen + UVA (PUVA)
  - narrow-band UVB
  - photodynamic therapy (PDT)
- Laser therapy
- Diphenylcyclopropenone or squaric acid dibutyl ester – medications that are applied to your scalp to produce an allergic reaction (an approach known as topical immunotherapy),
- Topical anthralin (a tar-like topical medication),
- Topical minoxidil (a topical medication approved for male and female pattern baldness).

Although many products are used for this condition, their effectiveness is uncertain.

You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

WHO IS PAYING FOR THIS STUDY?

A company called Aclaris Therapeutics, Inc., the sponsor of the study, is paying for this study.

<<Quorum may add site-specific conflict-of-interest language to the form based on information the site reports to Quorum.>>

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It will not cost you anything to participate in this study.

HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can proceed, your participation will include 7 visits to the study center and will last about 28 weeks, up to a maximum of about 200 days. Your first visit for this study may occur on the same day as Visit 9 on the ATI-501-AUAT-201 study.

You will visit the study center to have the procedures and tests described in this form. Ask the study doctor or study staff about your study visit schedule.

WHAT WILL HAPPEN DURING THIS STUDY?

The study doctor or study staff will give you study drug to put on your scalp. You will apply up to 4 mLs of the study drug 2 times a day (in the morning and evening approximately 12 hours apart) for 24 weeks. In addition, study participants with eyebrow loss may apply study medication to the entire eyebrows twice daily for 24 weeks.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor or study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.
- Use birth control during the study and up to 30 days after the last application of study drug.

What happens when I come for study visits?

After you sign this form, the study doctor or study staff will perform the tests and procedures listed below when you come in for the study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- **Demographic Questions:** Ask you to confirm personal information, such as your name, date of birth, sex at birth, and race/ethnicity.
- **Health and Medication Questions:** Ask you to answer questions about your health, your medical history, your alopecia areata history, and the medications you take.
- **Physical Exam:** The study doctor or a member of the study staff will examine your overall general appearance, head, eyes, ears, nose, throat, stomach, nervous system, muscles and bones, lymphatics, and skin, and will listen to your heart and lungs.
- **Vital Signs:** Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
- **Blood Testing:** Take some blood through a needle in your arm to do safety and laboratory tests. At visits where blood samples are collected, you will have 2 tubes of blood drawn. The maximum amount of blood you will have taken over 6 months is slightly more than 5 tablespoons for the safety testing.
- **Urine Testing:** You will have your urine tested.

- **Pregnancy Testing:** Test your urine to see if you are pregnant. You will only have pregnancy testing if you are a woman and can have children.
    - The study doctor or study staff will tell you if the pregnancy test results are positive.
    - The results of the pregnancy testing must be negative in order for you to be enrolled in and continue in the study.
- **Other Questions:** You will be asked about any changes in your health and the medications you are taking since the previous study visit.
- **Scalp Examinations:** The study doctor or study staff will examine your scalp to determine the amount of hair loss, the quality of your hair (by gently pulling at hairs at the border of areas of hair loss), and the appearance and severity of your hair loss.
- **Questionnaires:** You will examine your scalp to determine and describe the appearance and severity of your hair loss and assess the impact of hair loss on your life. At Visit 4 (Day 57) and Visit 6 (Day 169), you will be asked to rate your satisfaction with the study drug results.
- **Photography:** The study doctor or study staff will take pictures of your head and scalp (your face will be included in these photographs) to document the hair loss. These photographs may be used for research purposes related to the study and for presentation to government health authorities, such as the U.S. Food and Drug Administration (FDA), at scientific meetings, for scientific publications, for general corporate purposes, and may be used for marketing purposes. Your identity will not be revealed in these photographs. Your identifying features, (eyes, mouth, tattoos) will be hidden in the photographs. **You do not have to let the study doctor or study staff take photographs if you don't want to; however, if you decline to have these pictures taken, you will not be allowed to participate in this study.**
- **Study Drug:** You will be given a supply of study drug and instructions for how to apply the study drug.
- **Apply study drug in the office:** At visit 1 if the study doctor decides you are able to participate, the study staff will instruct you on how to apply the study drug. You will apply the study drug in the office under the supervision and guidance of the study staff.
- **Subject Instruction Sheet:** You will be given a written instruction sheet.

If you participate on the ATI-502-AA-203 study, your Visit 1 may be the same day as visit 9 in the ATI-501-AUAT-201 study. If that is the case, you will have a short set of assessments completed as shown in the table below. If the study doctor decides you may proceed, you will be given a supply of the active study medication and perform your first application in the doctor's office. If your Visit 1 for the ATI-502-AA-203 occurs more than 14 days after Visit 9 on study ATI-501-AUAT-201, some additional tests will need to be done in order for the study doctor to decide if you may continue on the ATI-502-AA-203 study.

Events and Tests	Treatment Period							Post-Treatment
	Visit 1 (same day as Visit 9 on ATI-501-AUAT-201)	Visit 1 (>14 days since Visit 9 on ATI-501-AUAT-201)	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
Informed Consent	✓	✓						
Demographics, Health History and Medication Review	✓	✓						
Physical exam		✓					✓	
Vital signs[3]		✓		✓	✓	✓	✓	✓
Blood for safety and urine test				✓	✓	✓	✓	✓
Urine test for pregnancy, if you are a woman and can have a baby		✓		✓	✓	✓	✓	✓
Scalp examination and measurement of hair loss		✓		✓	✓	✓	✓	✓
Questionnaire Completion		✓			✓		✓	✓
Treatment Satisfaction Questionnaire							✓	
Photographs of your head and scalp		✓		✓	✓	✓	✓	
Receive study drug and instructions	✓	✓	✓	✓	✓	✓		
Return used study drug			✓	✓	✓	✓	✓	
Apply study drug in office	✓	✓						
Other Questions	✓	✓	✓	✓	✓	✓	✓	✓

WILL BEING IN THIS STUDY HELP ME?

The study drug may help your alopecia areata, but there is no guarantee that being in this study will help you. Your alopecia areata might not get better or may even get worse while you are in this study. Information from this study might help researchers to better understand alopecia areata or come up with new tests or medications to help others in the future.

WHAT ARE THE RISKS TO ME IF I AM IN THIS STUDY?

You must be careful to avoid having the study drug run into your eyes because it could cause irritation.

In animal testing, the following temporary side effects occurred on the skin where ATI-502 was applied:

- Redness
- Swelling
- Skin peeling

Healthy volunteers took an oral form of ATI-502, and the most frequently reported drug-related side effects include:

- Headache
- Abdominal discomfort
- Decreased appetite
- Dizziness
- Somnolence (Sleepiness)
- Diarrhea
- Dry Skin
- Nausea
- Constipation
- Dyspepsia (Indigestion)
- Feeling hot
- Paresthesia (Pins and Needles sensation on the skin)

People who took FDA-approved oral medications similar to ATI-502 experienced:

- Infections (bacterial, viral, fungal, or other infections)
- Abnormal blood tests (decreases in white blood cells and platelets, and increases in liver function tests)
- Cancers
- Increased lipids (total cholesterol, high-density lipoprotein cholesterol [also known as HDL, the good cholesterol], and low-density lipoprotein cholesterol [also known as LDL, the bad cholesterol])

Since ATI-502 Topical Solution is an investigational drug, there may be other risks that are unknown. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

It is possible that using ATI-502 Topical Solution may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- A rash

- A fast pulse
- Sweating
- A feeling of dread
- Swelling around the eyes and mouth
- Swelling of the throat
- Wheezing
- Having a hard time breathing
- A sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Inability to breathe without assistance

You should get medical help and contact the study doctor or study staff, if you have any of these or any other side effects during the study.

What are the risks of giving blood for this study?

The study doctor or study staff will take your blood by sticking a needle in your arm. Some problems you might have from this are:

- Pain
- Bruising
- Dizziness
- Infection

Risks of study photography

There are no expected physical risks if the study doctor or study staff takes photos of your head and scalp during the study. It is possible that people who see the study photos will recognize you.

Loss of confidentiality

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

What are the risks if I am pregnant or nursing a child during the study?

If you are a woman who can have a baby, you must not get pregnant during the study or for 30 days after the last study drug application. In animal testing, there were potential toxic effects to both the embryo and fetus, indicating a risk to pregnancies. If you are pregnant or nursing a child while using ATI-502 Topical Solution, there may be risks to you, the embryo, fetus, or nursing child. Nobody knows what all the risks are right now.

If you are a woman who can have children, the study doctor or study staff will talk to you about birth control you must use during the study and up to 30 days after the last application of study

drug. If you are a sexually active male, you must agree to use a barrier method of contraception from the first application of study drug to at least 30 days after the last application of study drug.

If you think you are pregnant during the study, you must tell the study doctor or study staff immediately.

Women who become pregnant during the study will have to leave the study. The study doctor or study staff may ask for information about the pregnancy and the child's health at birth, and for up to 6 weeks after the birth, and may share this information with the sponsor.

What are the risks of fathering a child during the study?

If you are a sexually active male, you must not father a child during the study or for 30 days after the last dose of study drug. In animal testing, there were potential toxic effects to both the embryo and fetus, indicating a risk to pregnancies. There may be risks to an unborn embryo or fetus that you father during or after the study. Nobody knows what all the risks are right now.

You must agree to use a barrier method of contraception from the first dose of study drug to at least 30 days after the last dose of study drug.

If you think your partner is pregnant during the study, you must tell the study doctor or study staff immediately. The study doctor or study staff may ask for information about the pregnancy and the child's health at birth, and for up to 6 weeks after the birth, and may share this information with the sponsor.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I AM IN THIS STUDY?

It is possible that you could have problems and side effects of ATI-502 Topical Solution that nobody knows about yet, which include your alopecia areata getting worse.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

WILL I RECEIVE ANY NEW INFORMATION DURING THE STUDY?

If the study doctor or study staff learns any new information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If, during the course of this study, any injury occurs to you as a direct result of the administration of the study drug or properly performed procedures, the Sponsor agrees to pay all medical expenses necessary to treat such injury: 1) to the extent you are not otherwise reimbursed by medical insurance; and 2) provided you have followed the directions of the study doctor.

The compensation offered by the Sponsor for any injury which occurs to you as a direct result of the administration of the study drug or poorly performed procedures by the study doctor or study

staff, will be paid after the Sponsor receives all appropriate documentation and completes its review, to its satisfaction, of all documentation regarding your claim for injury.

You will not lose or give up any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for negligence or intentional misconduct by signing this consent document.

There are no plans to provide financial compensation for such things as lost wages, disability, or discomfort due to injury.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

WILL I RECEIVE PAYMENT?

<<Quorum will add site-specific compensation language to the form based on information the site reports to Quorum.>>

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits except for benefits having to do with the study. If you want to stop being in the study, tell the study doctor or study staff.

The study doctor or study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if, for example:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. The study doctor or study staff may ask you to participate in some procedures or tests to help you leave the study safely and/or to collect more information for the study.

If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity will be protected as required by law and according to any policies the study center or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared as needed for the study. For

example, the U.S. Food and Drug Administration (FDA), the sponsor, and Quorum Review may look at your study and medical records.

Your blood and urine samples will not be labeled with your name or other directly identifying information. Your samples will have a code (a unique subject identifier) instead. The list that matches the code with your name will be stored separately from your samples. Your samples will be kept only until we are able to complete the tests described in this form, and then your samples will be destroyed.

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.

WHO CAN I TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.QuorumReview.com.

> Quorum Review is located in Seattle, Washington.
> Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
> Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

HOW WILL MY INFORMATION BE USED AND SHARED FOR THIS STUDY?

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study doctor and study staff will collect, use, and share health information about you, including any information needed to do the study and other identifying information about you, such as your name, address, phone number, or social security number. The information used and shared will include:

- information from your medical records

- information collected about you during the research, including study visits, notes, tests, procedures, photographs, etc.

Your information may be used and shared with these people for the following purposes:

- The study doctor and study staff to conduct this research.
- The sponsor, Aclaris Therapeutics, Inc.; people who work with or for the sponsor; and other researchers involved in this study. These people will use your information to review the study, to check the safety and results of the study drug, and to seek government approval of ATI-502 Topical Solution.
- Others required by law to review the quality and safety of research, including the FDA, Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries, and Quorum Review.

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study.

If you cancel your authorization, the study doctor and study staff will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years.

_____ _____

Signature of Participant Date

<<Quorum staff: Include the following for Indiana sites:

In **Indiana,** you must complete the following information:

_____

Participant's Street Address

_____

Participant's City, State, ZIP>>

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

For your safety, you or the study doctor should tell your regular health care provider that you are in this study. This is recommended so that your primary care doctor may contact the study doctor if they have any concerns or questions about your care.

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:

_____ _____

Name of Doctor Phone

☐ 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.

CONSENT

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I do not give up any of my legal rights. I will get a signed copy of this consent form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

I attest that I or my representative discussed this study with the individual providing consent.

_____
Signature of Principal Investigator or Sub-Investigator