INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

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Protocol No.: CCCR 08-2018

Sponsor: Afecta Pharmaceuticals
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Please read this form carefully. Take all the time you need to read, understand, and ask questions about any and all study procedures that will take place during the research study. The research study doctor or research staff members can explain words, procedures, or information where you are concerned. This form is intended to provide you with the information towards your decision to participate or refuse participation. Please know that at **any** time you may choose not to participate in the research study; your participation is completely voluntary. If you choose to participate you must sign your name at the end of this form.

YOU CANNOT UNDERGO ANY PROCEDURES FOR THIS RESEARCH STUDY UNTIL YOU SIGN THIS FORM

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Subject Initials: _____-_____-_____

Date: _____/_____/_____
MM DD YYYY

IRB #: U.S.IRB2018CCCR/08
Valid Until: September 10, 2019

I. TITLE OF RESEARCH

A Double-Blind, Pilot Study to Evaluate the Efficacy and Safety of Topical AFX 5931 in the Treatment of Mild to Moderate Hand Dermatitis

II. DESCRIPTION OF THE RESEARCH STUDY

You are being asked to participate in a single-site research study to determine the efficacy and safety of Topical AFX 5931-A in the treatment of mild to moderate hand dermatitis.

The objectives of this research study will be to measure the efficacy, tolerability and the safety of topical AFX 5931-A in the treatment of mild to moderate hand dermatitis in subjects 12 years of age or older.

Following informed consent, study eligibility criteria will be reviewed prior to enrollment in this research study. The Hand Eczema Severity Index and Investigator's Global Assessment will be conducted at the screening visit. You will be randomized to receive treatment with either Topical AFX 5931-A or the control vehicle. This study will require the application of the topical medication twice daily during the course of the study.

In this research study we will ask you to come up to 4 visits over a period of 28 days. Before the beginning of this research study we will ask you to sign this document to determine that you understand what is being done in this research study, that questions were answered for you, and that you are willing to participate in all the research being asked of you.

III. COMPANY IN CHARGE OF THE RESEARCH STUDY

A company called Afecta Pharmaceuticals, the research study sponsor, is paying for the research study.

IV. DURATION OF THE RESEARCH STUDY

If you decide to participate in the research study **and** the research study doctor agrees you are an appropriate candidate to be included in the research study, your participation will last up to approximately 28 days including the screening and end of study visits. You will have to come to the research study center up to 4 times over these 28 days. The research study staff will tell you when to come in for your research study visits. You should ask the research study staff how long your visits will last and about your research study visit schedule. It is important for you to be able to attend all research study visits, so be sure to discuss the schedule with the research study staff.

V. COST OF PARTICIPATION

While you are in the research study, you will still need to have regular medical care. You (and/or your health care payer) will be billed for the costs of your regular medical care that are not part of the research study.

You do not have to pay for the treatment or assessments that are part of the research study. To find out more about the cost of participation, you should ask the research study doctor or research study staff.

VI. COMPENSATION FOR PARTICIPATION

You will be paid $50 per each visit you complete, for a maximum of $200 for 4 visits. If you are unable to complete the research study, if you voluntarily leave the research study, or if the research study is stopped early, you will be paid a pro-rated amount for visits completed. You will be paid upon your completion of participation, within 30 days of your last visit.

VII. SUBJECT PARTICIPATION

Before you can start the screening portion of the research study, the research study doctor or research study staff will talk to you about the research study. If you agree to be in the research study, you will have to sign this consent form.

After screening, if the research study doctor says you can be in this research study and you want to be in this research study, you will be assigned to one of the following groups.

1. Active Treatment: Topical AFX 5931-A
   - This treatment cohort will be required to apply the investigational product twice per day, every morning and night during the course of the study.
2. Vehicle Control
   - This treatment cohort will be required to apply the investigational product twice per day, every morning and night during the course of the study.

What happens when I come for research study visits?

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

- **Health and Medication Questions:** Ask you to answer questions about your health and your medical history including injuries, illnesses, surgeries, and the medications, vitamins, and dietary supplements you take.

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- **Demographic Questions:** Ask you to give personal information, such as your date of birth, gender, race, ethnicity, etc.

- **Physical Exam and Vital Signs:** Examine general appearance, skin, heart/cardiovascular, lungs and abdomen. Record vital sign measurements, perform assessments, and take photographs.

- **Photographs and Assessments:** Digital photographs will be taken at proximal and distal views of the dorsal as well as palmar surfaces of the hand

- **Pregnancy Test:** Women of childbearing potential (WOCBP) must use an effective method of birth control or must be post-menopausal or surgically sterile. Women of childbearing potential (WOCBP) must have a negative urine pregnancy test (UPT) at Visit 2 (Baseline).

At the Screening visit, your research study doctor will identify and grade your hand dermatitis. The investigational product is required to be applied twice per day during the course of the study.

While you are in the research study you must:

- Follow the instructions you are given;
- Come to the research study center for all appointments with the research study doctor;
- Tell the research study doctor or research study staff about any changes in your health or the way you feel;
- Not receive any treatment in the selected area from another doctor without informing the research study doctor;
- Tell the research study doctor or research study staff if you want to stop being in the research study at any time.

VIII. BENEFITS AND RISKS OF PARTICIPATION

The investigational product is a treatment for mild to moderate hand dermatitis. The anticipated clinical benefit is improvement in hand dermatitis using the topical medication, AFX 5931-A.

There are risks associated with all types of research. The possible side effects of the topical AFX 5931-A include temporary burning, stinging, irritation, and itching at the application site. This is a research study that aims to evaluate the efficacy and safety of topical AFX 5931-A in the treatment of mild to moderate hand dermatitis.

You are advised to not participate in this study if you have a history of sensitivity to any of the ingredients in the investigational product.

Are there risks to me if I am pregnant or nursing a child during the study?

If a woman is pregnant or nursing a child while using Topical AFX 5931-A there may be risks to the unborn baby or nursing child. Nobody knows what these risks are right now.

If you are female and are capable of having children, you may be eligible to be in this research study but it is important to monitor your urine for signs that you may be pregnant and that you use contraception while you are in this research study. Your research study doctor will advise you which forms of contraception are acceptable for this research study and when and for how long you must use the contraception. Some examples of contraception are: oral/implant/injectable or transdermal contraceptives, intrauterine device (IUD), condom with spermicide, or diaphragm with spermicide. **Some methods of birth control will not work when you are taking certain drugs.**

The research study doctor will require women of childbearing potential who join this research study to have pregnancy tests during this research study. A pregnancy test does not keep you from becoming pregnant.

If you think you are pregnant during this research study, you must tell the research study doctor immediately. If you become pregnant while you are in this research study, you will be followed-up until delivery or termination of pregnancy. The research study doctor may share this information with the sponsor and U.S. IRB, the Institutional Review Board (IRB) that oversees this research study for the rights and safety of participants.

IX. ILLNESS OR INJURY

If you get hurt or sick as a direct result of being in the research study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the research study doctor or research study staff.

In addition, you or your health care payer will be billed for any costs of diagnosing and treating a condition or injury that may occur during the research study if:

- The sponsor and/or the research study doctor do not think the condition or injury is a direct result of you being in the research study; and/or,
- You have not followed the directions given to you by the research study doctor or research study staff during the research study.

You can ask the research study doctor or research study staff to find out more about costs.

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

You do not give up any of your legal rights by signing this consent form.

X. STATEMENT OF VOLUNTARY PARTICIPATION

Your participation in the research study is completely voluntary. You can decide not to be in the research study and you can change your mind about being in the research study at any time. There will be no penalty to you, and you will not lose any benefits associated with the research study (aside from participation in the research study and future visit stipends). If you want to stop being in the research study, tell the research study doctor or research study staff and return all or any research study materials.

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

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

XI. ALTERNATIVE THERAPY

You do not have to participate in the research study to receive treatment for hand dermatitis. Your alternative is to seek other therapies and not participate in the research study.

XII. CONFIDENTIALITY

Your confidentiality will be protected as required by law and according to any policies the research study center or sponsor may have. As you first enter into the research study, your identity in the research study will be de-identified using a numbering system that only this investigator, research study members, and sponsor are knowledgeable of. Be aware that your research study records (which include your medical records, your signed consent form, and other information) will be shared and copied as needed for the research study. If you have questions about this, please ask the research study doctor.

The research study doctor or research study staff or sponsor may use some details about your participation in the research study in books, magazines, journals and scientific meetings. If this happens, your personal information will be de-identified.

XIII. SHARING OF STUDY-RELATED INFORMATION

This section explains who will use and share your private health information if you agree to be in the research study. If you do not sign this consent form, you cannot be in the research study.

During the research study, the research study doctor and research study staff will use, collect, and share health information about you (your "records"). Your records may include any information about you that the research study doctor needs to do the research study and other identifying information about you, such as your name, address, phone number, or social security number. Your records will include:

- Medical records
- Medical history
- Photographs

Your health information will be used or shared when required by law. Your records may be used and shared with these people for the following purposes:

- The research study doctor and research study staff to conduct the research described in this consent form.
- The sponsor, Afecta Pharmaceuticals, parties who work with or for the sponsor; and other researchers involved in the research study. These parties will use your records to review the research study, and to check the safety and results of the research study.
- Others required by law to review the quality and safety of research, including: the U.S. Food and Drug Administration (USFDA), Department of Health and Human Services (DHHS), Office of Human Research Protections, other government agencies in the United States and other countries, and U.S. IRB: a group of people who review research studies to protect the rights and welfare of research participants.

The sponsor will make every effort to maintain the privacy of your health information and there are national and state laws that require the research study doctor to protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the research study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes.

No publication or public presentation about the research described in this consent will reveal your identity.

You have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the research study. If it is necessary for your care, your records will be provided to you or your regular doctor.

You can cancel this authorization to use and share your records at any time. If you want to cancel your authorization, you must write a letter to the research study doctor. If you cancel your authorization, you will not be able to continue in the research study.

Even if you cancel your authorization and leave the research study early, the research study doctor and research study staff will still be able to use and share your records that they have already collected as described above.

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.

You will receive a signed copy of this consent form.

XIV. RESEARCH STUDY CONTACT

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 the research study. Contact the research study doctor or research study staff as soon as possible.

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

If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the research study doctor or research study staff, of if you have any concerns or complaints about the research study, you may contact:

U.S. Investigational Review Board, Inc.® (U.S. IRB, Inc.®)
6400 S.W. 72nd Court, Miami, Florida 33143
Telephone: (786) 473-3095
Email: rmvf1550@aol.com

XV. PHOTOGRAPHS

By signing this consent form, I hereby authorize the taking of photographs with the understanding that such photographs may be used for publication, education, research, and advertising purposes. I hereby transfer the exclusive right to use and authorize others to use all or any part of such photographs for any educational purpose, any advertising purpose, to copy the material onto all other formats and media, and the right to broadcast the program over any television station. If and when the photographs are used, they will be de-identified. This authorization is considered part of the Privacy Health Care Notice provided to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This authorization will remain in effect until we receive written notification to terminate agreement signed and dated by the subject.

XVI. CONSENT

I have read this consent form, and I have been able to ask questions about the research study. The research study doctor or research study staff has talked with me about the research study. They have answered all my questions. I voluntarily agree to be in the research study. I agree to allow the use and sharing of my study-related records as described above.

By signing this consent form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

_____
Printed Name of Subject/Participant

_____ _____
Signature of Subject/Participant (if an adult) Date

DO NOT SIGN ABOVE IF LESS THAN 18 YEARS OF AGE

If subject/participant does not have the legal capacity to consent their participation:

I am the parent/guardian of the subject/child named above and I consent to his/her participation in the research study described above.

_____
Printed Name of Parent/Guardian

_____ _____
Signature of Parent/Guardian Date

I attest that the parent/guardian named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed for the subject/child to be in this research study:

_____
Printed Name of Person Explaining the Consent

_____ _____
Signature of Person Explaining the Consent Date

I attest that I discussed this research study with the parent/guardian named above.

_____ _____
Signature of Principal Investigator or Sub-Investigator Date

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Subject Initials: _____-_____-_____ Date: _____/_____/_____
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XVII. ASSENT FOR SUBJECTS 12 TO 17 YEARS OF AGE

This informed consent form contains important information to help you decide if you want to be in this research study. If you have any questions that are not answered in this informed consent form, ask the research study doctor or research study staff.

I have read this form, and I have been able to ask questions about the research study. The research study doctor or research study staff has talked with me about the research study. They have answered all my questions. I voluntarily agree to be in the research study. I agree to allow the use and sharing of my study-related records as described above.

By signing this consent form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

_____ _____

Printed Name of Subject/Child for Assent Age (years)

_____ _____

Signature of Subject/Child for Assent Date

I confirm that I have explained this research study to the extent that is compatible with the subject/child's understanding, that the subject/child had enough time to consider this information, had an opportunity to ask questions and voluntarily agreed to be in this research study.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date

I attest that I discussed this research study with the subject/child named above.

_____ _____

Signature of Principal Investigator or Sub-Investigator Date

For further information regarding your rights as a volunteer, contact Rosa M. Fraga, Chairperson of the U.S. Investigational Review Board, Inc.® (U.S. IRB, Inc.®) at 786-473-3095 or rmvf1550@aol.com.