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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 05/12/2025

Protocol Number: 2021P000648



INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: An open-label proof of concept study regarding the efficacy and safety of dupilumab in the treatment of keloids
PRINCIPAL INVESTIGATOR: Martina Porter, MD
PROTOCOL NUMBER: 2021P-000648

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you have a diagnosis of Keloids.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Why is this research being done?
The study is being done to see how well the study drug, Dupilumab will work to help people with keloids.

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TITLE OF RESEARCH PROTOCOL: AN OPEN-LABEL PROOF OF CONCEPT STUDY REGARDING THE EFFICACY AND SAFETY OF DUPILUMAB IN THE TREATMENT OF KELOIDS
PRINCIPAL INVESTIGATOR'S NAME: MARTINA PORTER, MD
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How long will the research last and what will I need to do?
We expect that you will be in this research study for 26 weeks with 11 onsite visits. Screening and baseline visits will take 3 hours, follow up visits will last up to 1 hour.

You will be asked to questions regarding your keloid and medical history, blood will be drawn at first visit and Vital signs will be taken at each visit and keloid lesions will be photographed. You will be administered the study medication as a subcutaneous injection and given injection training for at home drug administration. You will also be asked to maintain a paper diary to record home-drug administration. Up to 5 participants will be given the option to provide skin biopsy samples at two visits.

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

Is there any way being in this study could be harmful to me?
Common risks of being in the study could be insomnia, joint pains, immune reaction, injection site reaction, allergic reaction, inflammation of the eyes, infection.

More detailed information about the risks can be found under ***"*RISKS AND DISCOMFORTS*".***

Will being in this study help me in any way?
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Martina Porter and is funded by Regeneron Pharmaceuticals, Inc. The funding agency in this study Regeneron Pharmaceuticals, Inc. is paying Beth Israel Deaconess Medical Center, Dr. Martina Porter and Dr. Hye Jin Chung to perform this research. BIDMC or Drs. Porter and Chung have no additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

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If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Martina Porter at [617] 667-5834.

PURPOSE

The study drug involved in this study, Dupilumab is investigational. The purpose of the study is to understand safety and efficacy of using dupilumab in patients with keloids. This means that the study drug is still being tested in research studies and is not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study. This particular investigational agent, Dupilumab has been approved by the FDA for use in other diseases or conditions, but we do not yet know if it is useful or safe as a treatment for Keloids.

STUDY PARTICIPANTS

You have been asked to be in the study because you have a diagnosis of Keloids.

Approximately 25 people will take part in this study at Beth Israel Deaconess Medical Center. BIDMC is the only site for this study.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be in this research study for about 26 weeks.

After you sign the consent form, the following things will happen:

The study has 3 periods:

- Screening period (up to 4 weeks before you receive your first dose of study drug)
- Treatment period (24 weeks)
- Follow-up period (4 weeks)

1. Screening Period (Visit 1, approx. 3 hours): Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include:

    - Test your urine for pregnancy, if you are a female of child bearing potential. Pregnant women can't take part in this research study.
    - Take your medical history, including any medications you are currently taking or have taken in the past. You will need to tell the study doctor about all medications or therapies you have used for your keloids in the past, even if you are not using them now.

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- Physical exam**,** may include a measurement of your weight, height, blood pressure, heart rate, body temperature
- Examine and grade your keloids.
- Have blood drawn (to test your blood counts, electrolytes, kidney and liver function tests, HIV screening, Hepatitis B screening, Hepatitis C screening, and tuberculosis screening test)
- Take photos of your Keloids.

2. Treatment Period (8-9 visits, approx. 1-3 hours per visit): Visits will occur every two weeks through week 4, then every four weeks through week 24, (if you choose not to pursue skin biopsy) or week 26 (if you choose to pursue skin biopsy). If you qualify to take part in this research study, you will undergo these research procedures:

   - If you are a female of child bearing potential, test your urine for pregnancy. Pregnant women can't take part in this research study.
   - Ask you about any changes in your health and medications since your last visit.
   - Physical exam**,** may include a measurement of your weight, height, blood pressure, heart rate, body temperature
   - Examine and grade your keloids.
   - Questionnaires: you will be asked to rate your keloid and how it impacts your quality of life
   - Blood for routine laboratory tests: have blood drawn to test your blood counts, electrolytes, kidney and liver function tests
     - The amount of blood collected at each visit is as follows
       - Screening: approximately 16 milliliters
       - Visit 24 – approximately 8 milliliters
       - In total approximately 24 milliliters will be collected
   - Take photos of your keloids.
   - You will also be required to maintain a drug diary to ensure compliance. You will be asked to bring completed drug diary at each in person visit.
   - If you decided to get the optional skin biopsy, sample will be taken from one area where you have keloid.
   - Suture removal after 2 weeks if any stitches placed. If gel foam is placed, no suture removal will be needed.

Administration of study drug

- You will receive Dupilumab as a subcutaneous (under the skin) injection (2 ready-to-use syringes (600 mg) at initial visit (week 0), and 1 ready-to-use syringe (300 mg) subcutaneously every 2 weeks until week 22 in healthy skin.
- The study drug will be administered in Clinical Research Center (CRC) at BIDMC for the first

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three times (weeks 0, 2, 4). Patients and/or caregivers will be trained on drug administration at weeks 2 and 4.

- You will receive drug in the CRC administered by study personnel at weeks 8,12,16,20 and will self-administer at home by you or your caregivers at weeks 6,10,14,18,22. If you or caregivers request, we will provide supervision through video visits.

Home Study Drug Administration:

- During home study drug administration weeks if you or your care giver wants a study physician to supervise or do another injection training a brief video visit can be conducted. No other research activities will be conducted except supervision of injection administration.
- If a visit will be conducted by video conference, the study staff will provide you with instructions. Study staff will launch the video conferencing in a private and secure area. To protect your privacy, we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment.
- We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit

Photos:

Your photos will be taken with a professional camera provided by Canfield and sent to them for analysis. The photos will be used to measure how long and wide the keloid lesions are. Photos will be stored for atleast 6years and destroyed upon PI's request from the canfield database. All photos will be shared without identifiers and coded with your unique subject ID. No readily identifying photos/images or information will be disclosed. Identifying aspects such as tattoos, moles, skin tags might be visible in the photo.These photos / images or parts of them may be used for publication and/or education. If so, your identity will not be disclosed.

3. <u>Monitoring/Follow-Up Period (One telephone call, approx. 30 min)</u>. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures.

   You will be asked to complete one remote study visit that will occur over the phone. You will receive a phone call from our study staff at Week 26 or 4 weeks after your last study drug administration. During this phone call, we will ask about any changes in your health and medications since your last visit.

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4. Early Termination Visit

If you stop or you are withdrawn from the study, you will be asked to return for an early termination visit. The procedures at this visit will be as outlined in the table below.
If you have completed at least 12 weeks of the study, a repeat optional biopsy will be offered. Photographs will be taken at the visit if it is around the time photographs were to be repeated.

Optional Skin Biopsy

Up to 5 subjects will undergo optional punch biopsies at baseline and week 24. One 4 mm punch biopsy will be obtained from the lesional keloid skin, only in subjects (up to 5) who consent to optional skin biopsy. Skin biopsy location will be determined by the investigator and standard procedures for skin biopsy will be employed. Subjects may have lesions closed with suture or gelfoam, depending on nature of lesion and biopsy. The specimen will be sent to BIDMC Research Core Facilities for further processing. Samples will be preserved in formalin jars and sent to the histology lab to be processed. The paraffin blocks will be sectioned and stained at the BIDMC histology, and then blocks and slides will be returned to the BIDMC, Department of Dermatology and stored securely at Department of Dermatology. Samples are retained for the duration of the project, through publication. The samples will be destroyed by the PI after 10years.
Would you like to participate in the optional skin biopsy?

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

SCHEMA/SCHEDULE/TABLE:

	Screen	Wk 0	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 18	Wk 20	Wk 22	Wk 24	Wk 26	FU call Wk 26	Early termination
Informed Consent	✓																
Inclusion/Exclusion	✓	✓															
Demographics/Medical History	✓																
Keloid History	✓																
Complete Physical Examination including height and weight	✓													✓			
Vital Signs	✓	✓	✓	✓		✓		✓		✓		✓		✓			✓
HIV, Hepatitis B (Hep B Sag, Hep B Sab, Hep B Cab) and Hepatitis C Screening (Hep C ab), TB Screening	✓																

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CBC with differential, BUN/Cr and AST/ALT	✓													✓			✓
Pregnancy Test (Urine)	✓	✓	✓	✓		✓		✓		✓		✓		✓			✓
POSAS/VSS assessment, size measurement	✓	✓		✓		✓		✓		✓		✓		✓			✓
DLQI		✓		✓		✓		✓		✓		✓		✓			✓
Digital photography of lesions		✓		✓		✓				✓				✓			✓
Adverse Events			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Skin biopsy (up to 5 volunteers)		✓												✓			✓
Suture removal*			✓												✓		
Medication Administration in CRC		✓	✓	✓		✓		✓		✓		✓					
Medication Administration at Home					✓		✓		✓		✓		✓				

Information and Biological Samples

Your information and biological samples will be used and shared with Regeneron Pharmaceuticals Inc. the sponsor and the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

Storing of Identifiable Information and Samples for Future Use

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At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored with identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future research of keloids. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

<u>More Common</u>

Immunologic: Antibody development (5% to 16%; neutralizing: 2% to 5%). This means that your body's immune system may make proteins, also known as antibodies, after being exposed to dupilumab. Some of these antibodies may be against dupilumab, neutralizing or inactivating dupilumab.

- Local: Injection site reaction (6% to 18%)

<u>Less Common</u>

- Central nervous system: Insomnia (1%)
- Gastrointestinal: Oral herpes simplex infection (4%), gastritis (2%), toothache (1%)
- Hematologic & oncologic: Eosinophilia (≤2%)
- Infection: Herpes simplex infection (2%)
- Neuromuscular & skeletal: Joint pains (3%)
- Ophthalmic: Conjunctivitis (2% to 10%), eye pruritus (1%)
- Respiratory: Oropharyngeal pain (2%)

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Rare

<1%, these side effects were reported after dupilumab was approved by the FDA for the general population. Some of these side effects are from case reports, where doctors describe unique medical cases in published medical journals: Anaphylaxis, dry eye syndrome, eosinophilic granulomatosis with polyangiitis, eosinophilic pneumonitis, erythema nodosum, hypersensitivity reaction, keratitis, serum sickness, serum sickness-like reaction, significant cardiovascular event, inflammation of blood vessels (vasculitis)

Live Vaccine Risks: Live vaccines should not be given while you are taking dupilumab.

Skin Biopsy Risk:
Risks associated with skin biopsies include pain, bruising, risk of bleeding, and infection. In rare cases, some people may have an allergic reaction to the medication used to numb the area (lidocaine). Symptoms of an allergic reaction can include shortness of breath, difficulty breathing, rash, or hives. Any patient with a history of reaction to local anesthetic will be excluded from the study. There is also a possibility of your keloids becoming larger at the site of skin biopsy.

Reproductive Risks of Dupilumab
Available data from case reports and case series with Dupilumab use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus. There are adverse effects on maternal and fetal outcomes associated with asthma in pregnancy. In an enhanced pre- and post-natal developmental study, no adverse developmental effects were observed in offspring born to pregnant monkeys after subcutaneous administration of a homologous antibody against interleukin-4-receptor alpha during organogenesis through parturition at doses up to 10-times the maximum recommended human dose.

PREGNANCY

Because of the effects of this (these) study medication(s) on the developing fetus is (are) not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first dose of the study medication(s).

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant.

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The methods of highly effective birth control for this study are below:

1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately. Participants who become pregnant during the course of the study will immediately be withdrawn from the study, and the study doctors may ask to monitor your pregnancy, your health, and your baby's health after you are withdrawn from the study.

If you are a man capable of fathering children, you must use adequate contraception while participating in this study. For the purposes of this study, adequate birth control means;

1. use of a condom
2. Your partner must use an approved method of birth control as listed above.

Other Risks Related to Study Procedures

- **Blood Tests:** The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

- **Subcutaneous (SC) Injection:** A needle will be used to inject the medicine in the tissues under your skin, causing a small hole or puncture. For most people, needle punctures for SC shots do not cause any serious problems. Sometimes they may cause bleeding or bruising where the shot is given. Sometimes people complain of discomfort, infections, and/or pain at the site of the shot. Infection may happen with SC shots because the needle breaks the skin. Then germs can get into the skin underneath. Shots may cause abscesses or skin and soft tissue infections. Additionally, if a blood vessel is hit by the needle, the risk of infection will be even greater if germs are taken into the blood system.

- **Surveys/Questionnaires**: Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

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- **HIV testing:** Because the results of the HIV test done as part of this study may become a permanent part of your medical record, and because disclosure of a positive HIV test may have a negative impact on your insurability, employment, and social relationships, you may wish to seek a private confidential HIV test before enrolling in this study. Again, if you choose to enroll in this study even after having the HIV test done privately, the HIV test will be done again as part of your participation in the study and therefore the results may become a permanent part of your medical record. HIV is the cause of AIDS (the Acquired Immunodeficiency Syndrome). A positive test result means that you are infected by HIV, but does not tell you that you have AIDS. For antibody tests, a negative test usually means that a person is not infected. However, it can take 3 to 6 months for the HIV antibody test to become positive after infection. Having an HIV test is voluntary; however, if you choose to participate in this study HIV testing must be done to assure your safety (for example, in circumstances where a study drug would potentially have a negative effect on your ability to fight off infection and disease if you are HIV positive), to establish whether you are eligible to participate, and/or for other reasons required by the research protocol. If you choose not to have HIV testing, you will not be able to participate in this study. Massachusetts state law requires that you provide verbal informed consent before diagnostic testing for HIV is performed, and additional information relevant to the decision whether to get tested may be provided to you in connection with receiving the test; you are free to ask questions specifically about the implications of HIV testing.

  If you decide to participate and agree to be tested for HIV, the results of the HIV testing will be entered into your study chart in **Dr. Martina Porter's** office, and may also be added to your medical record. Information derived from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, including the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) where applicable, and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center, with protection of confidentiality so far as permitted by applicable law. Your physician is required by law to report positive HIV test results to health officials, including the Massachusetts Department of Public Health (MDPH) HIV/AIDS Surveillance Program. Reports to the MDPH will include your full name, address, medical record number, social security number, date or birth and gender. These reports may also include information about your medical history, health condition, and treatment. Your written approval is not required for this mandatory reporting, assuming you agree to participate in this study and receive an HIV test as a result of that participation. In general, releases of your HIV test results outside BIDMC (with the exception of required reporting to public health officials) require your written informed consent. By signing this form, you agree that those individuals who need to see your medical information, including the results of your HIV test, in order to conduct the study (including the BIDMC researchers, any collaborators, the sponsor of the study, the BIDMC Committee on Clinical Investigations and other groups that oversee the research at BIDMC, and the government agencies that have jurisdiction over the research) may receive the results of your test.

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By signing here you acknowledge that all of your questions have been answered and you consent to the release of your HIV test results by BIDMC as necessary to complete the research study.

_____

Patient name (print): **Date**

Loss of confidentiality

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY
Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the drug manufacturer, Regeneron Pharmaceuticals Inc., accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD
A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

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PRINCIPAL INVESTIGATOR'S NAME: MARTINA PORTER, MD
PROTOCOL #: 2021P-000648

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OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the following options:

1. Intralesional Steroid Injections
2. Intralesional 5 Fluorouracil injections
3. Pulse Dye Laser
4. Surgery with Radiation Therapy
5. Silicone Gel or Sheeting

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for appropriate tests, procedures, medications that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

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PAYMENTS TO YOU:

You will be paid for the following: $75 per scheduled study visit from Screening to Week 24 and an additional $100 for visits where a biopsy is performed (Week 0/baseline and Week 24 or Early Termination Visit).

If you complete the entire study, the total payment will be in the amount of $675. If you complete both biopsies, you will receive an extra $200. Payment will be made by check after at the end of each visit. Your payment will be prorated based on the number of visits that you completed.

You will be reimbursed for the following: $20 for parking for each visit.

It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section "Who to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on 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.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

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As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information, including photographs of the keloids. These photos/images will be stored securely in a way that will protect your privacy. They will be kept for a period of time required by the study. These photos / images or parts of them may be used for publication and/or education. If so, your identity will not be disclosed. No readily identifying photos/images or information will be disclosed. Identifying aspects such as tattoos, moles, skin tags might be visible in the photo.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and photographs of your face, as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study Regeneron Pharmaceuticals Inc. and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Other research collaborators and supporting research team members taking part in this study

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- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Martina Porter at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of

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your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN
Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI
If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS
You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

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I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____