



Subject's Name:
Title of Research Protocol: A pilot study evaluating the safety and efficacy of deucravacitinib compared to placebo in the treatment of moderate-to-severe Hidradenitis suppurativa (HS).
Principal Investigator's Name: Alexa Kimball, MD, MPH
Protocol #: 2023P000400



INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

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 moderate-to-severe Hidradenitis Suppurativa (HS).

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, deucravacitinib (BMS-986165) will work to help people with moderate-to-severe Hidradenitis Suppurativa. Hidradenitis Suppurativa is a painful, chronic, skin disease characterized by recurrent inflamed nodules (lumps) and abscesses (pus-filled lumps).

How long will the research last and what will I need to do?

We expect that you will be in this research study for 16 weeks with 6 onsite visits and one follow up phone call. Screening and baseline visits will take 3 hours, other visits will last up to 1 hour, and the phone call will be 30 minutes.

You will be asked questions regarding your Hidradenitis Suppurativa and medical history. Blood will be drawn at baseline, week 4, and week 16 visits. Targeted Physical exam, including height and weight and vital signs such as blood pressure, pulse rate (heart rate), and body temperature will be taken at first visit (screening) and Week 16. During the onsite visits, you will be asked to complete a quality of life questionnaire (DLQI) and Visual Analog Scale (VAS) for pain. The study medication and placebo are oral drugs and you will also be asked to maintain a paper diary to record home-drug administration. Oral drugs will be taken twice daily, once in the morning and in the evening for 16 weeks. You will be given an option to have digital photographs taken of your HS lesions at baseline, week 4, week 8, week 12 and week 16. Live vaccines should not be given while you are taking deucravacitinib.



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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 acne, nasopharyngitis (common cold), headache, diarrhea, nausea, and upper respiratory tract 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. Alexa Kimball and is funded by Bristol Myers Squibb. The funding agency in this study Bristol Myers Squibb is paying Beth Israel Deaconess Medical Center (BIDMC), Drs. Alexa Kimball and Martina Porter (a co-investigator on the study) to perform this research. Neither BIDMC or Drs. Kimball and Porter have additional interests in this research project or in the funding agency.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

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

PURPOSE

The study drug involved in this study, Deucravacitinib (BMS- 986165) is investigational. Deucravacitinib (BMS- 986165) is a tyrosine kinase 2 (TYK2) inhibitor that is involved in the Janus kinase- Signal Transducers and Activators of Transcription (JAK-STAT) pathway of inflammation. The purpose of the study to understand safety and efficacy of Deucravacitinib (BMS- 986165) in patients with moderate-to-severe Hidradenitis Suppurativa compared to placebo. This means that the study drug is still being tested in research studies and is



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not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study. This particular investigational agent, Deucravacitinib (BMS- 986165) has been approved by the FDA for use in other disease or conditions (such as moderate-to-severe plaque psoriasis at a dose of 6 mg once daily), but we do not yet know if it is useful or safe as a treatment for Hidradenitis Suppurativa. Psoriasis is also a chronic inflammatory skin condition like hidradenitis suppurativa (HS).

STUDY PARTICIPANTS

You have been asked to be in the study because you have a diagnosis of moderate-to-severe Hidradenitis Suppurativa.

Approximately 30 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 20 weeks. 30 subjects will take part in the study. 20 will get the study drug and 10 will get placebo.

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 (16 weeks)
- Follow-up period (4 weeks after last study drug dose (Week 20))

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:

- We will 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 Hidradenitis Suppurativa in the past, even if you are not using them now.
- Physical exam, may include a measurement of your weight, height, blood pressure, heart rate, body temperature
- Examine and grade your Hidradenitis Suppurativa
- Have blood drawn approximately 1.5 teaspoon (to test your blood counts, electrolytes, kidney and liver function tests, HIV screening, Hepatitis B screening, Hepatitis C screening, and tuberculosis screening test)

2. Randomization



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It is not clear at this time which of the study treatments, study drug or Placebo in this study would be better for you. For this reason, the treatment plan offered to you will be picked by chance [like the flip of a coin]. You will not be able to choose which treatment you receive. The chances of receiving either of the study treatments are approximately 2:1 to study drug or placebo. After the randomization, you will be assigned to one of the following groups:

A) Deucravacitinib group 6mg po bid for 16 weeks

B) Placebo group

If one study treatment arm is found to be less effective than the other while you are taking part in the study, you will be informed and further treatment will be discussed.

Placebo:

Depending upon the group to which you are assigned, you may receive a placebo instead of the study drug. A placebo is an inactive pill that looks like the study drug, but a placebo contains no active medication. Placebos are used to help determine if the results of the study are truly from the study drug. You will not know whether you will be receiving the study drug or the placebo. However, this information can be learned in case of an emergency.

Double-blind study:

Neither you nor your physician/research doctor will know which drug you are receiving. However this information can be learned in case of an emergency.

3. Treatment Period (5 visits, approx. 1-3 hours per visit): Visits will occur every two weeks through week 4, then every four weeks through week 16. 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, we will 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 Hidradenitis Suppurativa
- Questionnaires: you will be asked to rate your Hidradenitis Suppurativa 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
 - Baseline, Visit 4 and Visit 16 – approximately 1.5 teaspoons per visit



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- In total approximately 1.5 tablespoons will be collected
- Take photos of your HS, if you decided to get optional digital photographs of your HS lesions.
- 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.

Study Drug:

During your scheduled baseline, week 4, week 8 and week 12 visits, you will be given study medication to take home with you.

We advise you take the medication at the same time each day. One tablet in the morning and another tablet in the evening and record compliance in a daily diary. Deucravacitinib can be taken with or without food. Do not crush, cut, or chew the tablets.

On days you have an in-person study visit, please do not take your morning medication. You will take the medication after your onsite visit.

If you forget to take your medication, please record it on the paper diary.

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

You will receive a phone call from our study staff at Week 20. During this phone call, we will ask about any changes in your health and medications since your last visit.

Early Termination Visit

If you stop or you are withdrawn from the study, you will be asked to return for an early termination visit. This visit will occur within 2 weeks after study withdrawal. The procedures at this visit will be the same as at the Week 16 visit.

Schedule of Activities:

	Screening	Baseline	Wk 4	Wk 8	Wk 12	Wk 16	Wk 20 followup call
Informed Consent	X						
Inclusion/ Exclusion	X	X					
History/ Demographics	X						



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Targeted Physical Examination (examination of only certain parts of your body to confirm diagnosis)	X					X	
HS Assessments	X	X	X	X	x	X	
Labs: Hematology and Chemistry (blood counts and liver, kidney function tests)		X	X			X	
HIV, Hep B and C screening	X						
TB screening	X						
Erythrocyte Sedimentation Rate, C-Reactive Protein (inflammatory markers)		X	X			X	
Photographs (optional)		X	X	X	x	X	
Urine Pregnancy Test*	X	X	X	X	X	X	
Patient assessments		X	X	X	x	X	



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Adverse Events		X	X	X	x	X	X
Study Drug Administration		X	X	X	x		
Complete study drug diary		X	X	X	X	X	

*for women of childbearing potential only

Optional Photography

Your photos will be taken with an iPad approved by Beth Israel Deaconess Medical Center Information Systems support team. Photos will be stored for at least 6 years. All photos will be stored without your personal health information and will be coded with your unique subject ID. 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.

I agree to allow my photos to be taken for the study and to be stored for publication and educational purposes as described above: (please check and initial one to indicate your choice).

_____ YES _____ NO

Information and Biological Samples

Your information and biological samples will be used and shared with Bristol Myers Squibb the funding agency 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



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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.

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.

More Common [*>5% occurrence*]

upper respiratory infections (URI), including Nasopharyngitis ("common cold")

Less Common [*>1% but <5% occurrence*]

Increase in creatinine phosphokinase (a type of protein from muscles) in the blood,
herpes simplex infection, (i.e. "Cold sores")
mouth ulcers,
folliculitis (infection of hair follicles)
acne

Rare [*<1% occurrence*]

herpes zoster infection, also known as "shingles"
Diarrhea
Nausea
Cancer

Summary of known and potential risks and benefits

Deucravacitinib (SOTYKTU) has been studied extensively in both "Phase 2 and Phase 3 studies" for its use in psoriasis. These are required studies before bringing a medication to patients. The Phase 2 study had a smaller number of patients but assessed multiple doses (including the 6mg twice daily [BID] dose which this current study is using, in hidradenitis suppurativa). The Phase 3 studies had roughly 1700 patients and assess the dose of 6mg daily for psoriasis. You should discuss any side effects that may arise with the study team/your doctor immediately.

In the Phase 2 study, adverse events were reported in 51% of the patients in the placebo group and 55 to 80% of the patients in the active-drug groups, with the highest percentage in the group receiving 6 mg twice daily. There was a higher occurrence of mild-to-moderate acne in the active-treatment groups than in the placebo group, with 4 cases (9%) in the highest-dose group.



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Infections, including Tuberculosis

In psoriasis patients who take medications which act on the immune system (such as deucravacitinib) infections are often experienced. These tend not to be severe, and tend to resolve on their own. However, sometimes serious infections may occur. It is important that you inform your doctor of any signs or symptoms of infection. Herpes simplex virus (HSV) causes is the virus that can cause cold sores (oral/nasal) or genital rash. HSV is contracted by skin-to-skin contact with someone who already has the virus, even if they do not have the rash showing at the time of contact. Deucravacitinib does not cause HSV, but it can lower your body's ability to defend against HSV and it may decrease your body's ability to prevent and HSV rash if you have been exposed in the past and carry the virus.

Hypersensitivity

As with any drug, hypersensitivity reactions can occur with patients taking deucravacitinib, and it is impossible to predict who this may happen to. These can range from a mild to severe. In the larger studies called Phase 3 trials, there were few events of hypersensitivity associated with taking deucravacitinib.

Malignancy (Cancer)

In the Phase 2 studies, there was 1 case of malignancy (malignant melanoma in situ, Grade 0) that was reported on skin biopsy on Day 96. The event was considered mild and non drug-related by the investigator. In the larger Phase 3 trials, malignancies were rare and most events were considered not related to deucravacitinib use, or it was unclear if deucravacitinib played a role in the malignancy development.

Live Vaccine Risks: Live vaccines should not be given while you are taking deucravacitinib. Let all of your doctors know you are in a trial and receiving deucravacitinib before receiving any vaccine.

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.

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



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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.

If you believe your partner has become pregnant while you were taking the study medication, please inform the study team immediately.

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.
- **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.
- **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



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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. Alexa Kimball'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 of 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.

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, Bristol Myers Squibb, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the



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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.

OTHER AVAILABLE OPTIONS

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

1. Biologic Therapies (injectable or infused medications, such as as adalimumab, that decrease the immune system)
2. Oral retinoids (oral pills that are often used for acne and may decrease inflammation of the skin)
3. Other immunosuppressive agents (other medications that decrease the immune system)
4. Oral antibiotics
5. Surgery or other procedures to remove skin affected with HS

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.



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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.

Payments to You:

You will be paid for the following: \$75 per scheduled study visit from Screening to Week 16.

If you complete the entire study, the total payment will be in the amount of \$675. Payment will be made by check 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, 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.



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**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

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 Hidradenitis Suppurativa.

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 of this study Bristol Myers Squibb 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



Subject's Name:
Title of Research Protocol: A pilot study evaluating the safety and efficacy of deucravacitinib compared to placebo in the treatment of moderate-to-severe Hidradenitis suppurativa (HS)
Principal Investigator's Name: Alexa Kimball, MD MPH
Protocol #: 2023P000400



- 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. Alexandra Kimball 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 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



Subject's Name:
Title of Research Protocol: A pilot study evaluating the safety and efficacy of deucravacitinib compared to placebo in the treatment of moderate-to-severe Hidradenitis suppurativa (HS)
Principal Investigator's Name: Alexa Kimball, MD MPH
Protocol #: 2023P000400



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.



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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.

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.

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: _____



Subject's Name:
Title of Research Protocol: A pilot study evaluating the safety and efficacy of deucravacitinib compared to placebo in the treatment of moderate-to-severe Hidradenitis suppurativa (HS)
Principal Investigator's Name: Alexa Kimball, MD MPH
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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: _____