Department of Dermatology
David Koch Cancer Research Building II, Room 206
1550 Orleans Street,
Baltimore, Maryland 21287
410-955-8662 phone 410-614-0635 fax

JOHNS HOPKINS
MEDICINE

# Clinical Study Protocol

Sponsor: Pfizer Inc.

Protocol Title: A Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of Abrocitinib for Reducing Pruritus in Adults with Prurigo Nodularis and Chronic Pruritus of Unknown Origin

Brief Title: Efficacy of Abrocitinib for Reducing Pruritus in Adults with Prurigo Nodularis and Chronic Pruritus of Unknown Origin

| | |
|---|---|
| NCT Number: | NCT05038982 |
| IRB Number: | IRB00262268 |
| IND Number: | 152968 |
| Name of Investigational Product: | Abrocitinib |
| Phase of Development: | 2a |
| Indication: | Prurigo Nodularis and Chronic Pruritus of Unknown Origin |
| Protocol Date: | March 16, 2022 |
| ICF Date: | March 16, 2022 |

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

# COMBINED RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

**Protocol Title**: **A Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of Abrocitinib for Reducing Pruritus in Adults with Prurigo Nodularis and Chronic Pruritus of Unknown Origin**

**Application No.:** **IRB00262268**

**Sponsor/Supporter/Funded By:** **Pfizer, Inc.**

**Principal Investigator**: **Dr. Shawn Kwatra, MD**
**Department of Dermatology**
**Johns Hopkins School of Medicine**
**601 North Caroline Street, Suite 8033**
**Baltimore, MD 21287**
**Tel: 410-502-7546**
**Fax: 410-502-2309**

---

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

## 1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- This research is being done to evaluate how effective an investigational study drug called abrocitinib is and how safe it is in reducing the signs and symptoms in patients with prurigo nodularis or chronic pruritus of unknown origin (CPUO)
- All participants will receive 200 mg of abrocitinib to be taken as a daily oral dose.
- Your participation in this study is anticipated to last for up to 20 weeks (to account for screening). During this time, you will be asked to make up to 7 in person study visits. You will

be asked to complete various study diaries in between these visits and you will take study drug daily from weeks 0 – 12.

- You will have tests, exams and procedures during the study that include physical examination, skin biopsies and blood collection
- There is a risk that you might experience discomfort or side effects with the use of the study drug or procedures. Some of them are still unknown at this stage. The study doctor is trained to take the appropriate measures to reduce risks and limit any discomforts you may experience.

## 2. Why is this research being done?

The purpose of the study is to evaluate how effective an investigational study drug called abrocitinib is and how safe it is in reducing the signs and symptoms in patient with prurigo nodularis or chronic pruritus (itching) of unknown origin (CPUO). There are currently no highly efficacious standard of care medications for treatment of prurigo nodularis or CPUO.

Abrocitinib is an immune modulating drug that targets Jak1 which is an important signaling protein that leads to production of proteins that may contribute to conditions of chronic itch. By interfering with Jak1, this drug may help decrease severity of disease for patients with these conditions. This drug has been investigated as a treatment for other skin conditions, including atopic dermatitis (eczema) and psoriasis. In addition to evaluating if this drug is effective and safe in the treatment of prurigo nodularis and CPUO, we'd also like to evaluate how this impacts certain biomarkers in the skin and the blood before and after study drug administration. This will help investigators understand how the immune system contributes to conditions like prurigo nodularis and CPUO and help to better inform future treatment options and ideas.

***Are there any investigational drugs/devices/procedures?***

The use of Abrocitinib in this research study is investigational. The word "investigational" means that Abrocitinib is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of Abrocitinib in this study.

***Who can join this study?***

People between the ages of 18 – 80 years with a diagnosis of prurigo nodularis or chronic prurigo of unknown origin (CPUO) may join.

## 3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

**Study Table:**

| **Examination** | **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** | **Visit 6** | **Visit 7** |
|---|---|---|---|---|---|---|---|
| **Week of Study** | **Screening Visit (-4)** | **Week 0** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | **Week 16** |
| Informed Consent | X | | | | | | |
| Review of Inclusion/Exclusion Criteria | X | X | | | | | |
| Medical History | X | | | | | | |
| Vital signs | X | X | X | X | X | X | X |
| Skin examination | X | X | X | X | X | X | X |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Questionnaires | | X | X | X | X | X | X |
| Photographs | | X | X | X | X | X | X |
| Dispense abrocitinib | | X | X | X | X | | |
| Itch Diary Review/compliance | | | X | X | X | X | X |
| Skin biopsy | | X | | | | X | |
| Blood Draw | X | X | X | X | X | X | X |
| | | | | | | | |
| | | | | | | | |

**Visit 1 - Screening Visit (4 weeks before study entry)**
At your screening visit, your eligibility for the study will be confirmed. This will entail:

- Physical examination: Examination of major body organs.
- Vital signs: Measurement of blood pressure, heart rate, respiratory rate, body temperature, height and weight.
- Blood collection to assess if you qualify for study entry. The total amount of blood to be taken in this study for each participant is approximately 130 mL (about 9 tablespoons). These samples will be used to test:
  - Hematology (blood count), biochemistry (tests of kidney, thyroid and liver function).
  - IgE (immunoglobulin E, an inflammatory marker)
  - Hepatitis B and C test.
  - HIV screening test. You may be asked to sign a separate State of Maryland consent form for this HIV test. If the HIV test is positive it does not always mean you are infected with the HIV virus. It does mean you will need further testing and you will receive counseling about this.
  - Pregnancy testing: only for women capable of having children: by blood test at the first study visit and urine sampling test every 4 weeks at site visit or at home.
    Only for participants with known history of HIV: CD4+ T cell count and viral load will be evaluated at screening and at the end of the study drug period. This will be approximately 10 mL (less than 1 tablespoon) blood in addition to total amount of blood.

- **For All Study Visits the following procedures will be done according to the schedule above:**
  - Dispensing of Investigational Drug: All participants will receive abrocitinib beginning at Visit 2. This will be taken as a daily oral dose of 200mg in tablet form. This . study drug administration will continue for 12 weeks .
  - Electronic diary: You will be asked to complete a diary daily in the morning. This will include questionnaires to evaluate the severity of your symptoms such as itch and pain, and asking you to rate your quality of sleep during the last night. The completion of the diary will take approximately 10 minutes. Your study doctor or site staff will train you how to use the diary during the Screening Visit (Visit 1) and give you instructions on how to complete these assessments. This diary must be returned to the site at the end of study visit.
  - Questionnaires: you will need to complete up to 6 questionnaires on a tablet. This will provide insight into how your disease is affecting your quality of life and to provide information on your symptoms and the impact of the disease on your life. Total duration of completion of these questionnaires will take approximately 30 minutes. Also, your study doctor will need to evaluate the severity of your symptoms and complete up to 2 questionnaires at each visit.
  - Physical examination: Examination of major body organs.

- Vital sign: Measurement of blood pressure, heart rate, respiratory rate, body temperature, and weight.
- Photographs: Photographs of the pruritic areas will be taken at each study visit.
- Skin biopsy: A 4 mm punch biopsy of the affected pruritic area will be taken at Visit 2 and Visit 6. This will involve injection of numbing medication followed by taking the biopsy. You will not feel pain, only pressure. A stitch will be placed and care instructions will be given. You will return for suture removal 7 to 10 days after the biopsy. This dot below shows the size of the biopsy to be performed.

- Blood collection at every visit. The total amount of blood to be taken in this study for each participant is approximately 130 mL (approximately 9 tablespoons). These samples will be used to test:
    - Hematology (blood count), biochemistry.
    - IgE (immunoglobulin E)
    - Biomarker testing – Biomarkers are measurable biological parameters, including protein or DNA levels, that may be indicators of certain conditions. Analyzing how biomarkers change may be helpful for researchers to better understand how to treat PN or CPUO.
    -

- **For Visit 7 – (Week 16 Follow-up Visit) the following procedures will be done according to the schedule above:**
    - Electronic diary: You will be asked to complete a diary daily in the morning. This will include questionnaires to evaluate the severity of your symptoms such as itch and pain, and asking you to rate your quality of sleep during the last night. The completion of the diary will take approximately 10 minutes. Your study doctor or site staff will train you how to use the diary during the Screening Visit (Visit 1) and give you instructions on how to complete these assessments. This diary must be returned to the site at the end of study visit.
    - Questionnaires: you will need to complete up to 6 questionnaires on a tablet. This will provide insight into how your disease is affecting your quality of life and to provide information on your symptoms and the impact of the disease on your life. Total duration of completion of these questionnaires will take approximately 30 minutes. Also, your study doctor will need to evaluate the severity of your symptoms and complete up to 2 questionnaires at each visit.
    - Physical examination: Examination of major body organs.
    - Vital sign: Measurement of blood pressure, heart rate, respiratory rate, body temperature, and weight.
    - Photographs: Photographs of the pruritic areas will be taken at each study visit.
    - Blood draw: the total amount taken in this visit for each participant is approximately 40 mL (approximately 3 tablespoons). These samples will be used to test:
        - Hematology (blood count), biochemistry.
        - IgE (immunoglobulin E)
        - Biomarker testing – Biomarkers are measurable biological parameters, including protein or DNA levels, that may be indicators of certain conditions. Analyzing how biomarkers change may be helpful for researchers to better understand how to treat PN or CPUO.

**Communicable diseases:**

The law requires us to report positive tests to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as

required by Maryland law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

**Photographs/Video recordings:**
As part of this research, we are requesting your permission to create and use photographs to help answer the research question. Photographs will not be used for advertising or non-study related purposes. Photos that are taken will not identify you (will not show your face or birth mark etc/tattoo).
You should know that:

- You may request that the photographs be stopped at any time.
- If you agree to allow the photographs then change your mind, you may ask us to destroy that imaging/recording. If the imaging/recording has had all identifiers removed, we may not be able to do this.

**Will research test results be shared with you?**
We will share the results of all standard lab tests (Hepatitis B, Hepatitis C, HIV and pregnancy testing (if applicable), blood counts and blood chemistry) with you.

It is uncertain if the other research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

**How long will you be in the study?**
You will be in this study for up to 20 weeks.

## 4. What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, urine, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required. Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

## 5. What are the risks or discomforts of the study?

**Foreseeable and known risks of Abrocitinib:**
There is a risk that you might experience discomfort or side effects with the use of the study drug. Some of them are still unknown at this stage. In some cases, **side effects can be serious, long-lasting, permanent, or life-threatening**. The study doctor is trained to take the appropriate measures to reduce risks and limit any discomforts you may experience.

Side Effects:
- The most commonly reported side effects are:
  - Nausea (1 in 7 people)
  - Nasopharyngitis (nasal discharge and sore throat) (1 in 8 people)
  - Headache (1 in 25 people)
- Rare but serious side effects include:
  - Serious infection (less than 1 in 100 people)
  - Vomiting (1 in 85 people)
  - Decreased platelet counts (which may increase risk of bleeding) (1 in 75 people)

**Risks of Study Procedures:**
*Skin Biopsy*
- Small risk of bleeding
- A scar may form, but is likely to fade over time. In rare cases, the scar will not heal and develop into a thick scar or keloid. (This is more likely to be a problem in people who have dark skin or have a tendency to develop keloids.)
- All procedures have a small risk of infection

*Blood Draw*
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

*Interviews or questionnaires*
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

**Identifiable private information**
There is the risk that information about you may become known to people outside this study.

**Unknown risk**
There may be side effects and discomforts that are not yet known.

## 6. Are there risks related to pregnancy?

Participants who are of child bearing potential are asked to use 2 forms of contraception or practice abstinence to avoid becoming pregnant during the course of the study. Participants of child bearing potential will be screened for pregnancy at the screening visit and before beginning study drug administration.

If a participant becomes pregnant during the course of the study, they will be removed from the study. We will ask to follow the participant to monitor the outcome for the participant and child.

It is unknown whether this research may hurt an embryo or fetus.

## 7. Are there benefits to being in the study?

You may or may not benefit from being in this study.

If you take part in this study, you may help others in the future.

## 8. What are your options if you do not want to be in the study?

You do not have to join this study. Other options include continuing with current treatment options under your current care.

If you do not join, your care at Johns Hopkins will not be affected.

## 9. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

## 10. Will you be paid if you join this study?

You will receive up to $400 for successful completion of the study. You will receive $50 for completion of the screening visit (Visit 1) and Visits 3, 4, 5 and 7, and $75 for completion of study visits 2 and 6. You will receive a check at the end of the study visit or a check will be mailed to your home address.

You will also receive reimbursement for parking costs.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

## 11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 13. How will your privacy be maintained and how will the confidentiality of your data be protected?

**HIPAA Authorization for Disclosure of Protected Health Information**

**What information is being collected, used, or shared?**
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

**Who will see, use or share the information?**
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

**Do you have to sign this Authorization?**
You do not have to sign this Authorization, but if you do not, you may not join the study.

**How long will your information be used or shared?**
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

**What if you change your mind?**
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

**How will your information be protected?**
We will make all efforts to protect your information. All participants will be assigned a unique identifier and the key linking this to you will be kept in a secure location only accessible to the primary investigator. All information will be stored on secure servers with restricted access.

## 14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

## 15. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

**What is the Institutional Review Board (IRB) and how does it protect you?**
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

**What should you do if you have questions about the study, or are injured or ill as a result of being in this study?**
Call the principal investigator, Shawn Kwatra at 410-955-7546. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Shawn Kwatra, MD at 410-955-7546 during regular office hours and at 410-955-5933 after hours and on weekends and ask to speak to the on-call dermatology resident.

## 16. Optional Study Components

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

**Future Contact**

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

**Please sign and date your choice below:**

**YES** ☐ _____ _____
Signature of Participant Date

**NO** ☐ _____ _____
Signature of Participant Date

## 17. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

## WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

| Signature of Participant | (Print Name) | Date/Time |
|---|---|---|

| Signature of Person Obtaining Consent | (Print Name) | Date/Time |
|---|---|---|

**I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.**

| Signature of Participant, LAR or Parent/Guardian | (Print Name) | Date/Time |
|---|---|---|

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

## DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

**My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.**

| Signature of Physician/Mid-Level Provider | (Print Name) | Date/Time |
|---|---|---|

| Signature of Participant | (Print Name) | Date/Time |
|---|---|---|

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**