Informed Consent Form to Participate in a Research Study
And Authorization to Use and Disclose Protected Health Information

Sponsor / Study Title:	**Suzhou Connect Biopharmaceuticals / "A Randomized, Double-Blind, Placebo-Controlled, Multi-Centered Study of the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of CBP-201 in Adult Subjects with Moderate to Severe Atopic Dermatitis"**
Protocol Number:	**CBP-201-WW001**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Invitation:

You are being asked to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our study team members will go through the consent form with you and answer any questions you have.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please read this consent form carefully and take as much time as you need to decide whether or not you want to take part. You may want to discuss your participation with family, friends or your General Practitioner (GP)/ Family Doctor.

PART 1

1. What is the purpose of the study?

You are invited to take part in a clinical research trial ("study") of an investigational drug called CBP-201 that is being developed for the treatment of moderate to severe atopic dermatitis. "Investigational" means that the study drug is not approved for sale in the United States by the U.S Food and Drug Administration (FDA) and that it is still being studied to evaluate how it works, and also to find out how effective and safe it is. The study is designed and funded by Suzhou Connect Biopharmaceuticals, Ltd.(also called 'Sponsor' in this consent form).

Scientists believe that a small particle called Interleukin 4 (or IL-4 for short) and Interleukin 13 (or IL-13 for short play a role in diseases such as atopic dermatitis (AD), a common, inflammatory skin disease. The investigational drug, CBP-201, is an antibody which is being developed as a treatment for AD and other atopic diseases. An antibody is a protein that is made by the body as a defense reaction against viruses and bacteria or other small particles. In this case, CBP-201 will act against both IL-4 and IL-13 by binding to their common receptor. By blocking these two mediators that contribute to a type of inflammation that plays a major role in AD, asthma and chronic rhinosinusitis with nasal polyposis, CBP-201 could possibly act against these diseases.

CBP-201 has already been studied in pre-clinical studies in animals and has been evaluated in one study in healthy adults. Another study with CBP-201 tested in subjects with moderate to severe AD has just completed.

The objective of this study is to test the efficacy and safety of CBP-201 in subjects with moderate to severe AD.

This study is a randomized, double-blind, placebo-controlled study. A placebo appears to be identical to the investigational drug but does not contain the active ingredient. Some subjects will receive the placebo so the Sponsor can evaluate the difference in effect between the placebo and the active study drug ("placebo-controlled"). "Randomized" means that whether or not you will receive the investigational drug or the matching placebo is completely left up to chance, like the flip of a coin. "Double-blind" means that neither you nor your study doctor will know whether or not the study drug or placebo is given to you. However, this information will be immediately available to your study doctor if required for medical reasons.

2. Why have I been invited?

You have been invited to join this study because the diagnosis of your condition indicates that you may meet the criteria to be in this study for the investigational product being tested, to help determine if there is any benefit from being treated with the study drug. In total, approximately 220 subjects will participate in approximately 60 study sites across the world.

3. Do I have to take part?

It is up to you to decide whether or not to join the study. If you agree to take part, we will ask you to sign and date a consent form. If you do not sign and date the consent form, you will not be able to join the study. You can leave the study at any time, without giving a reason. If you decide not to join the study or leave the study after you start the study, this will not affect the future benefits to which you are otherwise entitled.

4. What will happen to me if I take part?

The study has 3 main phases: Screening Period, Study Treatment Period, and Follow-up Period. If you agree to participate in this study, we will ask you to sign and date this consent form. During the screening period, you will be assessed, and tests will be done to determine if you qualify to participate in the study. If you qualify, the study treatment period will start and you will be asked to visit the study doctor's institution ("site") at least 15 times, as a minimum, during the following 6 months. Several examinations or procedures will be performed, some of which are usually not part of the normal care provided by your regular doctor. You will also be asked to complete some questionnaires during the study.

- **<u>Screening Period (Day -45 to Day -1):</u>**

Before the investigational drug can be given to you: The Screening Period is to determine if you are eligible to take part in the study. You will be asked to sign and date this consent form. You will be asked to temporarily discontinue certain prohibited medications. At Screening, the following initial assessments will be performed:

- Collect demographic details
- Collect medical history
- Document medication use, and previous medical procedures and treatments
- Physical examination, height, and body weight

- Electrocardiogram (ECG - a tracing of your heart's electrical activity)
- Investigator skin lesion assessments
- Safety evaluation
  - Assessment of adverse event (AE) and serious adverse event (SAE). AE/SAE means bad side effects.
  - Vital signs (VS) to include heart rate, breathing rate, blood pressure and body temperature
- Laboratory tests:
  - Blood will be drawn to assess your general health, such as complete blood count, routine kidney and liver function, and to screen for Hepatitis B, Hepatitis C and Human Immunodeficiency Virus (HIV). The study doctor may be required by law to report the result of these tests to the local health authority
  - If you are a woman of child-bearing potential a blood pregnancy test will be done. A urine sample may be collected for a urine pregnancy test just before being assigned to a study treatment regimen.

The total amount of blood to be taken during the entire study will be around 215 ml (approximately between 6-16 ml per visit). This corresponds to about 15 tablespoons and is not harmful for your health. You should know that during a normal blood donation about 450mL can be collected.

- You will be asked to complete 3 questionnaires about your quality of life and your skin condition.
- You will be instructed to assess your itch by completing an itch diary each day and to bring it back to the next on site visit.
- You will be instructed to apply bland lotion twice daily to affected areas starting at least 7 days prior to the Baseline Visit to the study completion visit.

You will be asked to return to the study site within 45 days of your Screening visit. Your test results and diary will be reviewed to determine if you qualify to participate in the study.

- **Study Treatment Period:**

After the Screening assessments have been performed and your eligibility is confirmed, you will be randomly assigned (like a flip of a coin) to one of the 4 study regimens of CBP-201 at different doses or its placebo (same product without active ingredient). This process is called "randomization". Neither you, the doctor or the study staff will know to which group you have been assigned. You will have a 75% chance of receiving the active study drug.

Assessments to be conducted at Day 01:

- Confirm informed consent and eligibility for study participation (note this may require an updated medical history)
- Document any new or changed medications
- Review your daily itch diary
- Assessments any health changes since your last visit
- Focused physical examination may be completed to assess areas affected by AD and to evaluate any AEs (side effects)

- Document vital signs
- Obtain ECG
- Blood and urine will be collected from you:
    - to check your health
    - to check how much study drug is present in your blood
    - to check what the study drug does within your body
    - If you are a woman of child-bearing potential, a blood pregnancy test will be done unless the screening pregnancy test was done by the study site within the last 7 days. A urine sample may be collected for a urine pregnancy test just before being assigned to a study treatment regimen.
- Study doctor skin lesion assessments
- Complete questionnaires about your quality of life and your skin condition
- Randomization to study treatment regimen
- Receive subcutaneous (under the skin) injection of the investigational drug (CBP-201 or placebo, which will depend on the result of randomization at baseline)
- You will remain in the research site for at least 2 hours after the first study injection. The staff will assess your vital signs, the study injection site, and ask about any health changes since your injection.
- You will be reminded to complete your daily itch diary and to bring it back for the next on-site visit
- You will be instructed to continue applying the bland lotion twice daily to affected areas,
- The site will schedule the next on-site visit and remind you to perform required study procedures

Assessments to be conducted at Day 15/Week 2:

- Record vital signs
- Assessments of any new health changes since your last visit
- Focused physical examination may be completed to assess areas affected by AD and to evaluate any AEs
- Document any new or changed medications or treatments
- Review your daily itch diary
- Complete questionnaires about your quality of life and your skin condition.
- Blood and urine will be collected from you:
    - to check your health
    - to check how much study drug is present in your blood
    - to check what the study drug does with your body
- Study doctor skin lesion assessments
- Receive subcutaneous injection of investigational drug (CBP-201) or placebo
- You will remain in the office for at least 2 hours after the injection. The study staff will assess your vital signs, the study injection site, and ask about any health changes since your injection
- You will be instructed to continue to apply the bland lotion applications on affected

areas, twice daily.

- You will be reminded to complete your daily itch diary and to bring it back for the next on-site visit.
- You will be instructed when to return for the next visit and to perform required study procedures

Assessments to be conducted at Day 29/Week 4:

- Record vital signs
- Assessments any new health changes since your last visit
- Focused physical examination may be completed to assess areas affected by AD and to evaluate any AEs
- Document any new or changed medications or treatments
- Review your daily itch diary
- Complete questionnaires about your quality of life and your skin condition.
- Blood and urine will be collected from you:
    - To check your health
    - To check how much study drug is present in your blood
    - To check what the study drug does with your body
- Study doctor skin lesion assessments
- Receive subcutaneous injection of investigational drug (CBP 201) or placebo
- You will remain in the office for at least 2 hours after the injection. The staff will assess your vital signs, the study injection site, and ask about any health changes since your injection.
- You will be instructed to continue to apply the bland lotion applications on affected areas, twice daily
- You will be reminded to complete your daily itch diary and to bring it back for the next on-site visit.
- You will be instructed when to return for the next visit and to perform required study procedures.

Assessments to be conducted from Day 43/Week6 through Day113/Week16:

You will be asked to return to the study site on Week 6 (±2days) and every 2 weeks thereafter through Week 16 (±2days) for study treatment injection and the following assessments:

- Record vital signs
- Assessments any new health changes since your last visit
- Document any new or changed medications or treatments
- Review your daily itch diary
- Receive subcutaneous injection of investigational drug (CBP 201) or placebo.
- You will remain in the office for at least 30 minutes after the injection. The study staff will assess your vital signs, the study injection site, and ask about any health changes since your injection
- You will be instructed to continue to apply the bland lotion on affected areas, twice

daily.

- You will be reminded to complete your daily itch diary and to bring it back for the next on-site visit.
- Blood and urine will be collected from you:
    - to check your health (Week 8, 16)
    - to check how much study drug is present in your blood (Week 8, 12, 16)
    - to check what the study drug does with your body (Week 8, 12, 16)
    - pregnancy test if you are a woman of child-bearing potential (Week 8, 16)
- Study doctor skin lesion assessments (Week 8, 12, 16)
- Complete questionnaires about your quality of life and your skin condition (Week 8, 12, 16)
- Physical examination (Week 16)
- Focused physical examination may be completed at any week other than Week 16 to assess areas affected by AD and to evaluate any AEs.
- You will be instructed when to return for the next visit and to perform required study procedures.

- **<u>Follow-up Period:</u>**

After completing 16 weeks of study treatment with the study drug (CBP 201) or placebo, you will no longer receive any study treatment injections, but will be asked to return to the study site 5 times over an additional 8 weeks for follow-up visits (Week 17 plus or minus 3days, Week 18 plus or minus 3days, Week 20 plus or minus 3days, Week 22 plus or minus 3days and Week 24 plus or minus 3days). Note that Week 24 will be the final study visit.

- Record vital signs
- Assessments of any new health changes since your last visit
- Document any new or changed medications or treatments
- Review daily itch diary
- Assessment of your prior injection sites for any reaction (Week 17, 20)
- Blood and urine will be collected from you:
    - to check your health (Week 24)
    - to check how much study drug is present in your blood
    - to check what the study drug does with your body
    - pregnancy test if you are a woman of child-bearing potential (Week 24)
- ECG (Week 24)
- Study doctor skin lesion assessments (Week 20, 24)
- Complete questionnaires about your quality of life and your skin condition (Week 20, 24).
- Physical examination (Week 24)
- Focused physical examination may be completed at any week other than Week 24 to assess areas affected by AD and to evaluate any AEs.
- You will be reminded to continue to apply the bland lotion on affected areas twice

daily

- You will be reminded to complete your daily itch diary and to bring it back for the next on-site visit.
- You will be instructed when to return for the next visit and to perform required study procedures.

5. Expenses and payments

There will be no cost to you for taking part in this study. You will be provided with investigational drug, examinations, study procedures, and medical care related to the study at no charge.

6. Compensation for Participation

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

If you have any questions regarding your compensation for participation, please contact the study staff.

Reasonable costs for study related visits will be reimbursed. For this purpose, you will receive a set amount per visit as standard reimbursement for travel costs and meals. The study doctor will discuss details with you. If in individual cases, the travel expenses are higher than this, they can be reimbursed following prior discussion and approval. Please talk to your study doctor who will forward your request to the Sponsor. If these additional costs are approved, you will have to provide the receipts to document all reasonable costs (travel by taxi, bus, train, metro, and car parking) and will then be reimbursed. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

7. What do I have to do?

If you agree to participate, you will have to visit the study doctor for all study specific visits, and complete the required diary.

Additionally, you will not be permitted to:

- Take any other drugs or remedies, either by prescription or from the pharmacy or supermarket (including herbal and homeopathic preparations and dietary supplements) unless your study doctor has approved them.
- Take part in other clinical studies involving an investigational drug, be it a medicinal product, a medical device, or a procedure, while taking part in this study.

- Make any sperm donation (males only) during the screening period until the last follow-up visit.
- Participate in any unaccustomed strenuous activities during study participation.
- Make any blood donation (>450 mL) during the screening period until the last follow-up visit.

Woman of childbearing potential will have a blood pregnancy test done at screening (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study. Additional urine pregnancy tests will be done at baseline and weeks 8, 16 and 24. If sexually active, you must agree to use effective contraceptive measures throughout the entire study period.

Males who have not undergone a vasectomy must abstain from heterosexual activities or agree to use effective contraception throughout the entire study period.

Effective contraception options for participating subjects include:

i. Abstinence from sexual intercourse
ii. Using a condom, and a diaphragm or cervical cap, as well as use of a spermicidal (where available)
iii. Oral contraceptives (the “pill”) for at least 1 month prior to Baseline
iv. Depo-Provera or injectable birth control or implantable contraception (for example, Implanon)
v. Intrauterine device (IUD)

Should you have any questions about these precautions and warnings, please ask your study doctor.

8. What are the alternatives for treatment?

It is possible that by participating in this study your condition improves and that this study may be helpful in developing a new therapy for others with similar illnesses. However, it is also possible that you may not benefit from participation in this study.

Alternative treatments for your illness might be available. In case of additional questions, please consult your study doctor.

9. What are the side effects of any study treatment received when taking part?

<u>Side effects of the study drug</u>

To date, CBP-201 has been studied in the required animal safety studies and has been evaluated in a First-In-Human study in healthy adults as well as in a study of subjects who have been diagnosed with moderate to severe atopic dermatitis. The results of both of these studies have shown that CBP-201 is generally well tolerated.

In the First in Human study, there were no serious or severe side effects, nor were there any side effects due to laboratory abnormalities or electrocardiogram (ECG) changes or side effects leading to study discontinuation. The most common side effects that started after study drug treatment had begun were:

- Headaches
- Upper Respiratory Tract Infections

In the study of subjects diagnosed with moderate to severe AD, there were no serious adverse events (bad side effects) in any subject who was treated with either study drug or placebo nor were there any side effects due to laboratory abnormalities or electrocardiogram

(ECG) changes or adverse events (side effects) leading to study discontinuation. There were only 2 severe adverse events (itchiness in a subject receiving placebo and atopic dermatitis flare in a patient receiving active study drug) and neither were considered by the study doctor to be related to the study drug. The most common adverse events (bad side effects) that started after study drug treatment had begun were:

- Atopic dermatitis
- Upper Respiratory Tract Infections
- Headache
- Hay fever
- Nausea
- Asthma

Injection site side effects (a severe injection site reaction or a skin reaction to the study drug), were uncommon in both studies. If you experience a skin related side effect, you should inform your study doctor as soon as possible, whether or not you think it is related to your study treatment.

Placebo Risks

If you receive placebo (the inactive substance) as part of this study, your symptoms of Atopic Dermatitis, may not improve or may get worse.

Risks and discomfort associated with the study specific procedures

- Blood draws: Blood draws are normally done as part of routine medical care and present a slight risk of discomfort. Taking blood may result in a bruise at the puncture site, or less commonly fainting, swelling of the vein, infection and bleeding from the site. Procedures are performed under hygienic conditions by experienced personnel and care will be taken to prevent complications. The amounts of blood taken during this study involve no risk for your health, as long as you have neither donated blood nor lost more than 500 mL of blood in the 12 weeks before screening and during the study drug administration.

- Blood pressure and heart rate: An inflatable cuff will be placed on your arm and a machine will measure your blood pressure and pulse. You may experience mild discomfort in your arm while the cuff is inflated.

- Risks when taking an ECG: Although the ECG test itself is painless, being connected to the ECG machine involves preparation of the skin on the chest (such as shaving) in order to place the sensors. The sensors are sticky patches that are attached to the chest. Skin irritations are rare but could occur from the electrodes or gel that is used. The skin irritation usually disappears when the patches are removed.

- Administration of the study drug

There are possible side effects of study treatment and from tests done during the study. After the injection of the study drug you might experience side effects or discomforts. Subcutaneous injections can be associated with a local injection site reaction.

Signs and symptoms of an injection site reaction include, but are not limited to, pain, itching, redness and swelling of the skin.

During your study treatment visit you will be monitored for immediate reactions after each dose of CBP-201.

Discomfort with questionnaires
Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

10. What are the possible benefits of taking part?

There is no guarantee that you will receive a medical benefit from participating in this study. However, your participation in this study may help develop important scientific knowledge that could contribute to the development of a new drug product for treatment of severe atopic dermatitis.

11. What happens when the research study stops?

The Sponsor will not provide any additional care to subjects after they leave the study. Specific treatment for your condition would need to be considered by you and your doctor. Your study doctor may end your participation in the study early without your consent if it is in your best interest.

12. What if there is a problem?

You should tell the study doctor or study staff right away if you have any problems or concerns. More detailed contact information is given in Part 2.

13. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. More detailed information is given in Part 2.

Part 2 of the Information Sheet

1. What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your study doctor will tell you and discuss whether or not you should continue in the study. If you decide not to remain in the study, your study doctor will make arrangements for your care to continue. If you decide to continue in the study, he/she may ask you to sign and date an updated consent form outlining the changes.

2. What will happen if I don't want to continue in the study?

Taking part in this study is voluntary. You do not have to participate in this study. If you choose to take part, you can withdraw from treatment at any time. There will be no penalty to you, and you will not lose any benefits except for benefits having to do with the study. If you want to stop being in the study, tell the study doctor or study staff. If you decide to stop taking part in this study because side effects have occurred, it is important that you tell this to the study doctor or study staff.

The study doctor or Sponsor can remove you from the study at any time for a variety of reasons, even if you want to stay in the study. These may include reasons such as:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;

- If the study is cancelled; or
- For administrative reasons.

If you stop participating in the study early, the study doctor or study staff will ask that you document your notification of withdrawal in writing. They may also ask you some questions about your participation in the study and for you to have some end-of-study tests done for your safety. You are encouraged to complete the follow-up visits (without treatment) for safety purposes. Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.

If you change your mind later, you cannot withdraw your samples after they have been provided.

3. Primary Health Care Provider Notification Option

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

4. Whom do I call if I have questions or problems?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. In the event of an emergency, dial 911 immediately. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00042445.

5. Injury

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

The study doctor and the sponsor will decide if your injury was directly caused by taking the study drug or from procedures done for the purpose of this study. If you are injured as a direct result of taking the study drug or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. No other compensation, such as lost wages or compensation for discomfort due to injury, is offered by the sponsor. You will not be reimbursed by the sponsor for medical expenses related to the natural progression of your disease, illness, or condition, any other pre-existing condition, or any event that would have been expected from the standard treatment for your disease, illness or condition, or if the injury was the result of a failure to follow the study protocol or instructions or misconduct by the study doctor or study staff.

You will not lose any of your legal rights or release the sponsor, the study doctor, the study staff, or study site from liability for mistakes by signing and dating this consent form.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

6. Confidentiality

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this consent form. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

7. What will happen to any samples I give?

By consenting to take part in this study, you also consent to the collection and testing of your urine and blood samples for this research only. Your private information or urine and blood samples collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

8. What will happen to the results of the research study?

To maintain the integrity of this study, you generally will not have access to your personal data collected for the study until the study is complete. At the conclusion of the study and at your request, you generally will have access to your personal data maintained by the study doctor as described in the Notice of Privacy Practices provided to you by the study doctor. In

limited circumstance, such as if it is necessary for your medical care, your personal data may be made available to you earlier than as described in this form.

9. Who is organizing and funding the research?

A company called Suzhou Connect Biopharmaceuticals, Ltd. is the sponsor for this study and will pay the study doctor for including you in this study.

10. Statement of Consent

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Subject's Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research team will collect, use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Suzhou Connect Biopharmaceuticals, Ltd. and its affiliates.
- Representatives of IQVIA Biotech.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of the Person Obtaining the Authorization

_____ _____

Signature of the Person Obtaining the Authorization Date