INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of Study: Efficacy and safety of AbGn-168H in patients with moderate to severe active, anti-TNFα and/or anti-integrin refractory ulcerative colitis: a 26-week, open-label, multi-center, phase II proof of principle trial

Protocol Number: **2017.008.01**
Sponsor: **AbGenomics International Inc.**
Investigator: *(to be filled in at each site)*
Investigator Address: *(to be filled in at each site)*
24 Hour Telephone Number: *(to be filled in at each site)*

1. WHY HAVE YOU BEEN GIVEN THIS FORM?

You are being invited to take part in this research study. Before you decide if you want to participate, it is important for you to understand why the research is being done, how your information will be used, what the study will involve, as well as the possible benefits, risks and discomforts. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask the study doctor or study staff. Once the study has been explained and you have had all your questions answered to your satisfaction, you can decide if you want to be in this study or not. This process is called "informed consent." You will be asked to sign this form if you wish to participate. A signed and dated copy of this form will be given to you for your records.

Your decision to take part in this study is voluntary. You do not have to take part in this study. You will be free to withdraw from the study at any time without having to give any reason. A decision not to take part in this study, or to withdraw at any time, will not affect your health care. No promises can be made about how this study will affect your medical conditions, either positive or negative. People who take part in research are commonly referred to as "subjects" instead of "patients".

2. WHY ARE YOU BEING INVITED TO PARTICIPATE IN THIS STUDY?

You are being asked to participate in this study because you have developed ulcerative colitis (UC). Your doctors have determined that your UC is not responding to treatment with anti-TNF alpha or anti-integrin treatments, and that your UC can be classified as moderate-to-severe active ulcerative colitis.

3. WHAT IS THE BACKGROUND AND PURPOSE OF THE STUDY?

AbGenomics International, Inc (AbGenomics), the Sponsor of this study, has developed an investigational drug or study drug called Neihulizumab (AbGn-168H). Neihulizumab (AbGn-168H) will be referred to throughout this document as the "study drug." An investigational drug has not been approved by the United States Food and Drug Administration (FDA). The FDA allows Neihulizumab (AbGn-168H) to be used only in research studies like this one.

The purpose of this study is to understand the signs of efficacy (clinically or by laboratory measurement) and safety of the study drug in patients like you. This study will also look at the pharmacokinetics (PK) profile of the study drug in patients like you. Your PK samples tell us what your body does to process the drugs and how your body gets them out of your system.

In this study, you will receive a total of 8 doses of study drug over the period of 10 weeks. You will be given a dose of the study drug at 9 mg/kg. The study drug will be given to you by infusion (through a needle in your vein in your arm) and will last for approximately one hour.

By participating in this research study you do not give up any of your rights to alternative treatments that would otherwise be available to you.

What is Neihulizumab (AbGn-168H)?

Neihulizumab (AbGn-168H) is an antibody that is being evaluated in clinical studies in treating inflammatory disease and autoimmune diseases like psoriasis, psoriatic arthritis, Graft versus Host disease (GvHD) and UC. In two completed psoriasis trials and one psoriatic arthritis trial where multiple doses of 0.5, 3, 6 or 9 mg/kg of Neihulizumab (AbGn-168H) were administered, there were no safety concerns based on the data obtained. Neihulizumab was also conducted to treat patients with steroid refractory acute Graft versus Host disease (sr-aGvHD), where up to 4 infusions and up to 9 mg/kg of Neihulizumab were administered..

Neihulizumab (AbGn-168H) is produced by Boehringer Ingelheim Pharma GmbH & Co. K.G.

4. HOW MANY STUDY SUBJECTS ARE EXPECTED TO TAKE PART IN THIS STUDY?

Thirty-five (35) to 40 subjects, at approximately 15-20 centers in the United States will participate in this study. Here at (to be filled in by each site) we hope to enroll approximately (to be filled in by each site) subjects.

5. HOW LONG WILL YOU BE IN THE STUDY?

You will be in the study for up to 210 days (30 weeks):

- Once you agree to participate in the study you will enter the screening period. The screening period can last up to 4 weeks.

- Following the screening period, you will be scheduled for treatment if the study doctor decide that you are the right patient for this study.
- Following treatment, you will be monitored for 111 days for safety and to evaluate your response to the treatment.

6. WHAT ARE YOUR RESPONSIBILITIES AS A STUDY SUBJECT?

While in the study you must:

- Provide truthful information about your medical history and current conditions,
- Tell your Study Doctor about any medicines that you are taking: including what you are taking at the time you enter the study, that another doctor prescribes while you are on this study, or that you are taking without a prescription, including any herbal medicines, natural products and vitamins and any medications you may plan to take
- Females of childbearing potential must have a negative pregnancy test result prior to enrollment. Males and females of childbearing potential must agree to use a highly effective method of birth control during the study.
- Inform the Study Doctor as soon as possible if pregnancy occurs while you are on the study
- Follow instructions and come in for agreed-upon visits
- Tell the study doctor or staff about any changes in your health,
- Tell the study doctor or staff if you want to stop being in the study at any time

7. PROCEDURES

Screening Period (Day -28 to -1)

Once you have signed and dated this informed consent form, you will enter the screening period. The screening visit for the study must be completed before you are scheduled for study treatment. During this screening visit, the study doctor will decide if you are the right patient for this study. If you are a male, or a female of childbearing potential, you must agree to use a highly effective method of birth control during the study. In addition, to be in the study, you must not get pregnant, plan to be pregnant, impregnate another person, or breastfeed a baby. You also may not take part in another experimental treatment trial at the same time as this study. Following the screening visit, if you are eligible for and agree to take part in the study, you will be scheduled for treatment.

The following screening procedures will be done, to see if you qualify to participate in the study:

- Record information regarding your personal data, such as demographics (gender, age, height, weight, race, ethnicity), and any details about your UC (e.g. previous treatment), your medical and surgical history, and your current treatments.
- Full physical examination; including general appearance, HEENT (Head, Eyes, Ears, Nose and Throat), chest and heart, abdomen, lymph nodes, genitourinary, muscles , neurological, skin, and a rectal exam to test for blood in your stool
- Vital Signs, including body temperature, blood pressure, rate of breathing, heart rate and oxygen levels.

- An 12-lead electrocardiogram (ECG) (electrocardiogram) will be performed to measure the electrical activity of your heart.
- Flexible sigmoidoscopy: A test to check your rectum and lower part of your colon with a flexible tube inserted gently into the anus and advanced slowly into the rectum and the lower colon.
- Assessments including complete Mayo Clinic score and IBDQ (The Inflammatory Bowel Disease Questionnaire) will be performed to determine your UC activities. The Mayo Clinic score and IBDQ are common methods to evaluate your UC activity.
- Collect a small piece of your colon/rectum tissue to exam the changes of the tissue caused by UC. A staining of your colon/rectum tissue for the presence of Cytomegalovirus (CMV) will also be performed to determine whether you are infected by CMV.
- Collect your stool sample to test whether you have been infected by ova and parasites, pathogens, and *Clostridium difficile.*
- Collect your stool sample to test the level of calprotectin in your feces, which is an indication of intestinal inflammation.
- Collect a blood sample (about 1/2 tsps) to confirm the level of C-reactive protein (CRP, a marker of inflammation) in your blood.
- Collect a blood sample (about 1/2 tsps) for HbA1c test, which is an indicator for diabetes.
- Collect a blood sample (about 1 tsps) for safety laboratory assessments including hematology (blood count), and chemistry (elements and minerals in your blood).
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1/2 tsps) to diagnose the infection for tuberculosis.
- Collect a blood sample (about 1/2 tsps) for a pregnancy test, if you are of child bearing potential.
- Drug screening: urine samples will be collected to determine whether you have exposed to certain drugs.
- Viral screening: a sample of your blood (about 10 tsps) will also be used to determine whether you have been exposed to Epstein-Barr Virus (EBV), Hepatitis B and C (viruses that affect the liver and can cause chronic liver disease) and HIV (Human Immunodeficiency Virus), which is the virus responsible for causing AIDS (Acquired Immunodeficiency Syndrome). These tests are necessary to help determine the state of your health before you can participate in this study. A positive result from these tests will be reported to the local health department as required by state law. While expected to be confidential, these results, if disclosed, may affect your employment or health insurance options. The results of all these tests must be evaluated before you can receive any study medication. It is possible that after these tests are reviewed you will not be able to take part in this study; this will be evaluated on a case by case basis. There may be other reasons why you cannot participate. Your study doctor will discuss these with you.

If you qualify to participate in the study, your doctor will let you know the treatment arrangement of the study drug.

Treatment (Day 1)

The following assessments and/or tests will take place **before** you receive the study drug.

- Record and confirm information regarding your personal data; such as your weight and your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Full physical examination including general appearance, HEENT (Head, Eyes, Ears, Nose and Throat), chest and heart, abdomen, lymph nodes, genitourinary, muscles , neurological, skin, and a rectal exam to test for blood in your stool
- Vital signs
- An assessment to evaluate your UC activity (partial Mayo Clinic score).
- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1 tsps) for Pharmacokinetic (PK) and anti-drug antibody (ADA) tests at 15 minutes prior to infusion of the study drug.
    - PK samples tell us what your body does to process the drugs and how your body gets them out of your system.
    - ADA samples are used to test whether your body is developing antibodies against study drug. It is possible that your body may make antibodies against study drug. Antibodies are proteins made by the body that can make the drug ineffective.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

The Study Doctor will confirm that you are qualified to receive study drug. If you are eligible, you will receive a dose of the study drug through an intravenous catheter in a vein in your arm. This will take about 60 minutes to receive.

The following assessments and/or tests will take place **after** you start receiving the dose of the study drug:

- You'll be observed for any clinical adverse signs and be asked how you are feeling.
- Vital Signs will be measured at 30 mins, 1 hour and 1.5 hours after the start of infusion.
- Blood samples will be collected for PK testing at 2 hours after the end of infusion of the study drug (about 1/2 tsp)

Day 8, Day 15, Day 22 and Day 43

The following assessments and/or tests will take place **before** you receive the study drug.

- Record and confirm information regarding your personal data; such as your weight and your current treatments.

- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Partial physical examination
- Vital signs
- An assessment to evaluate your UC activity (partial Mayo Clinic score).
- Blood samples will be collected for PK testing at 15 minutes prior to the infusion of the study drug (about 1/2 tsp)
- Collect a blood sample (about 1 tsp) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

You will receive a dose of the study drug through an intravenous catheter in a vein in your arm. This will take about 60 minutes to receive.

The following assessments and/or tests will take place **after** you start receiving the dose of the study drug:

- You'll be observed for any clinical adverse signs and be asked how you are feeling.
- Vital Signs will be measured at 30 mins, 1 hour and 1.5 hours after the start of infusion.

Day 29 and Day 57

The following assessments and/or tests will take place **before** you receive the study drug.

- Record and confirm information regarding your personal data; such as your weight and your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Partial physical examination
- Vital signs
- An assessment to evaluate your UC activity (partial Mayo Clinic score).
- Collect your stool sample to test the level of calprotectin in your feces, which is an indication of intestinal inflammation.
- Collect a blood sample (about 1/2 tsps) to confirm the level of CRP in your blood.
- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1 tsps) for PK and ADA tests at 15 minutes prior to infusion of the study drug.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

You will receive a dose of the study drug through an intravenous catheter in a vein in your arm. This will take about 60 minutes to receive.

The following assessments and/or tests will take place **after** you start receiving the dose of the study drug:

- You'll be observed for any clinical adverse signs and be asked how you are feeling.
- Vital Signs will be measured at 30 mins, 1 hour and 1.5 hours after the start of infusion.
- On Day 29 only, blood samples will be collected for PK testing at 2 hours after the end of infusion of the study drug (about ½ tsp)

Day 71

The following assessments and/or tests will take place **before** you receive the study drug.

- Record and confirm information regarding your personal data; such as your weight and your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Partial physical examination
- Vital signs
- An assessment to evaluate your UC activity (partial Mayo Clinic score).
- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1/2 tsps) for PK tests at 15 minutes prior to infusion of the study drug.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

You will receive a dose of the study drug through an intravenous catheter in a vein in your arm. This will take about 60 minutes to receive.

The following assessments and/or tests will take place **after** you start receiving the dose of the study drug:

- You'll be observed for any clinical adverse signs and be asked how you are feeling.
- Vital Signs will be measured at 30 mins, 1 hour and 1.5 hours after the start of infusion.
- Blood samples will be collected for PK testing at 2 hours after the end of infusion of the study drug (about 1/2 tsp)

Day 84 (End of Treatment)

- Record and confirm information regarding your personal data; such as your weight and your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.

- Full physical examination
- Vital signs
- Flexible sigmoidoscopy
- Assessments to evaluate your UC activity (Complete Mayo Clinic score and IBDQ).
- Collect a small piece of your colon/rectum tissue to exam the changes of the tissue.
- Collect your stool sample to test the level of calprotectin in your feces, which is an indication of intestinal inflammation.
- Collect a blood sample (about 1/2 tsps) to confirm the level of CRP in your blood.
- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1 tsps) for PK and ADA tests.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

Day 112 and Day 140

- Record and confirm information regarding your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Partial physical examination
- Vital signs
- An assessment to evaluate your UC activity (partial Mayo score).
- Collect your stool sample to test the level of calprotectin in your feces.
- Collect a blood sample (about 1/2 tsps) to confirm the level of CRP in your blood.
- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1 tsps) for PK and ADA tests.

Day 182 (End of Study)

- Record and confirm information regarding your current treatments.
- You will be observed for any clinical adverse signs, and be asked how you are feeling.
- Full physical examination
- Vital signs
- Flexible sigmoidoscopy
- Assessments to evaluate your UC activity (Complete Mayo score and IBDQ).
- Collect a small piece of your colon/rectum tissue to exam the changes of the tissue.
- Collect your stool sample to test the level of calprotectin in your feces.
- Collect a blood sample (about 1/2 tsps) to confirm the level of CRP.

- Collect a blood sample (about 1 tsps) for safety laboratory assessments.
- Collect a urine sample for urinalysis test.
- Collect a blood sample (about 1/2 tsps) for anti-drug antibody (ADA) test.
- Collect a urine sample for a pregnancy test, if you are of child bearing potential.

8.

Your PK samples will only be used for the research purposes described in this form.

To protect your privacy, your samples will be labeled with your study number. The scientists doing the research will not know your identity.

Your samples may be sent to other members of the AbGenomics International Inc. group of companies, to contractors working for them and to regulatory authorities.

Your samples will be sent to a central laboratory in [Lab location]. The laboratory will securely store your samples. Your samples may also be shared with research partners for scientific research purposes. Before sharing with research partners, your samples will be labeled with a code number that is different from your study number. Your samples will not contain any personal identifiers. Your samples will not be sold, loaned or given to any other independent groups for their own use. Research partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The sponsor will control what is done with your samples.

Your optional samples may also be kept and used for up to 15 years. This will allow for the scientific research described above to be done in the future as new discoveries are made. The sponsor will ensure that your samples are stored securely. Your samples will be destroyed no later than 15 years. You will not be informed when they are destroyed.

9. DO YOU HAVE TO TAKE PART?

It is up to you to decide whether or not to take part in the study. You are free to refuse to participate. The decision you make is completely your own. You are free to leave and think about it or discuss it with your own doctor or family/relatives. Refusing to participate in this study will not change your regular medical treatment and care in any way. After you have decided to participate, you may change your mind and choose to withdraw from the treatment or the study at any time and for any reason. You are not required to explain your reasons for withdrawing. You can discuss with your doctor to make sure you understand what choices you have. If you withdraw, you will not suffer any penalty or loss of benefits regarding your future medical care.

If you choose to stop being a part of this study, the first step is to notify the Study Doctor immediately so that they can help you plan for your continued medical care. You will be asked to return for a final safety evaluation. For your safety, it is recommended that you go through the termination procedures (similar to procedures descried above for the “Day 182”, End of Study visit) any time you leave the study, and make arrangements for your

follow up care. At minimum, if you withdraw prior to Day 182 (End of Study), you will be asked to allow follow up until at least 28 days after the last administration of study drug.

The study doctor, Sponsor, regulatory authorities (FDA) or an independent ethics committee (IEC)/Institutional Review Board (IRB) may stop your participation in this study without your consent at any time if they feel it is in your best interest or if you cannot comply with study requirements.

The reason(s) for doing so (e.g., your own safety, study drug safety or Sponsor decision) will be explained to you, as well as advice about continued care for your condition, if this is appropriate. Also, the Sponsor has the right to stop the study for medical or business reasons. If this happens, all subjects participating in the study will be withdrawn.

10. WHAT ARE THE POSSIBLE RISKS?

There may be risks if you decide to take part in this study including the following:

- The possible risks of Neihulizumab (AbGn-168H) are:
    - Risk of hematopoietic cell depletion. This means that your body's ability to make new blood cells may be reduced. In studies of Neihulizumab in patients with an immune-mediated skin disease called psoriasis, a clinically insignificant, mild, and reversible decrease of white blood cells was seen at high doses.
    - Risk of impaired immune function. This means that you may be more susceptible to infectious diseases. However, in clinical trials that have been conducted with Neihulizumab so far, a higher infection risk has not been observed.
    - Risk of hypersensitivity (allergic) reactions. This means that you may have an immune reaction to the study drug. A severe hypersensitivity reaction could be life threatening. Some things that may happen during an hypersensitivity reaction are a rash, having a hard time breathing, wheezing when you breathe, sudden drop in blood pressure; feeling light-headed, swelling around the mouth, throat, or eyes, fast pulse and sweating
    - Risk of infusional toxicities. This means that you may experience symptoms of toxicity, from the dose of study drug you receive.
    - Risk of ileus. This means the movement of the intestines may slow down or stop. It can lead to a buildup or blockage of material from getting through the intestines.
    - Risk of secondary malignancies. This is the possible risk in aGvHD patient, which means that a new cancer may occur.

The study conducted in sr-aGvHD patients enrolled 4 subjects in total. The adverse events observed in this small group of subjects were consistent with what would be expected in this patient population. Most events were mild to moderate in severity and considered unrelated to study drug. There were no cytokine release reactions or infusion reactions observed with Neihulizumab and there was no apparent association between increasing dose of Neihulizumab and increasing incidence or severity of adverse events.

All of the subjects experienced at least one serious adverse event during the trial and 3 subjects died during the study. However, as noted previously, the prognosis in patients with steroid-resistant aGvHD is poor with mortality rates ranging up to 100%. The early deaths in this study are consistent with a patient population with severe disease and unlikely related to study drug treatment. This study was later terminated due to slow enrollment rate and the need for more safety monitoring, a new study was prepared to be able to more stringently monitor patients with sr-aGvHD.

You might benefit from this trial, if the drug works to improve your UC. The risks of participation in the trial include the risks associated with the study procedures (e.g. blood drawing and i.v. infusion) which are similar to other trials of the study drug. The specific risks that can be anticipated in subjects receiving Neihulizumab are described above. The study has been designed and will be conducted in such a manner as to minimize these risks as much as possible.

- Possible risks associated with the study procedures include:
    - You may have any of the possible side effects from inserting a needle into a vein used for collecting blood, including discomfort, infection, or bruising.
    - You have any of the possible side effects from electrocardiogram (ECG). The ECG is a procedure that requires you to lie still for a few minutes while electrodes are attached to your chest to record the activity of your heart. The ECG leads placed on your skin may cause slight redness to skin during their placement and removal.
    - You may have any of the possible side effects from flexible sigmoidoscopy examination and biopsy, including abdominal discomfort or pain, adverse reaction to the sedative used during the examination, bleeding from the site where a tissue sample (biopsy) was taken, and a tear in the colon or rectum wall.

It is possible that you may not feel any better while in this study. There could be unforeseen risks in being in this study that we do not know about yet. There also may be other side effects that we cannot predict. Any new information that we find out about during the course of this research and that could influence your decision to stay in the study will be given to your doctor and then to you, in a timely manner. Your doctor may order other tests and treatments if you need it for your disease. Any other tests or treatments will not be part of the study you are in.

If you are or become pregnant, or if your partner becomes pregnant, there may be unknown risks to the fetus. If you are a female who is of child bearing potential, you will be given a pregnancy test at screening, and if the result is positive, you will not be able to be in the study. If you are a sexually-active male or female, you must use a highly effective method of birth control such as abstinence, combined oral contraceptives, intrauterine device, implants, injectables or vasectomized partner throughout the study (until Day 182). The study doctor will discuss methods of birth control with you if needed. If you become pregnant, or think you may be pregnant during the study, contact

the study doctor's office **immediately**. You may be asked to withdraw from the study. You must not be breast-feeding an infant during the study. If you are male and received study treatment and your partner becomes pregnant, please inform the study doctor **immediately**. The study doctor must follow up and document the course and the outcome of all pregnancies, even if you withdraw from the study or if the study has finished.

11. WHAT ARE THE POSSIBLE BENEFITS?

You may or may not get any direct benefit from taking part in this study. Other patients with UC may benefit in the future as a result of this research. When we finish this study, we hope to better understand the safety and efficacy of Neihulizumab (AbGn-168H), in patients with moderate to severe active ulcerative colitis.

12. ARE THERE ALTERNATIVE TREATMENTS?

Your doctor will discuss your alternative treatment options and possible benefits and risks with you. By participating in this research study you do not give up any of your rights to alternative treatments that would otherwise be available to you. You do not have to be in this study to get treatment for your UC. Your doctor will discuss your treatment options and possible benefits and risks with you. This study is entirely voluntary. If you decide to participate in this study, you may change your mind at any time later, for any reason without penalty or loss of benefits to which you are entitled.

13. WILL YOU INCUR ANY EXPENSES OR RECEIVE ANY PAYMENTS?

AbGenomics, the Sponsor of the study, will cover the costs of the study drug and will be paying the study institution for work completed on this study. You will not be paid to participate in this study; however you may be reimbursed per hospital visit (up to <<please indicate maximum cost per local agreement>>) for your travel expenses as a direct result of participating in this study. Taking part in this study might lead to additional charges to you or your insurance company. You and your insurance company will not be charged for the cost of tests done solely for research purposes, such as those to determine the level of study drug in your bloodstream.

You or your insurance company will be charged for other portions of your care during these research studies that are considered standard of care. You may be responsible for co-payments and deductibles that are standard for your insurance coverage.

Before you agree to be in this study, the study staff will contact your health care payer to see if your plan will cover the costs required as part of your participation. To find out more about costs, you can ask the study doctor or study staff.

>

14. WHAT IF YOU ARE INJURED DURING THE STUDY?

If, during the course of the study, you have an injury as a direct result of the study treatment(s) and you have followed the directions of your study doctor, the Sponsor will pay any medical expenses necessary to treat such research-related injury that are not first

covered by your medical or hospital insurance, or from third party or governmental programs providing such coverage. The Sponsor will not provide direct monetary compensation for any side effect or injury that is not related to the study drug or treatment. The Sponsor will not make any financial compensation for things such as lost wages, disability, emotional distress, physical injury or discomfort arising out of or related to your participation in this study, the study drug or the treatment. In addition, medical expenses from illness or injuries that are not directly related to the study treatment are your personal responsibility. The medical people at the hospital where you are participating in this study will give you emergency medical care if it is necessary. You will need to pay for the cost of such care, either personally or through your medical coverage.

If you experience any unexpected symptoms or injury, and if emergency medical treatment is required, please report it immediately to:

_____

(Site to insert contact name and number)

15. WILL INFORMATION ABOUT YOU BE KEPT CONFIDENTIAL?

By signing this form you consent to the study doctor and his or her staff collecting and using your personal information for the study. This includes: your date of birth, your sex, your ethnic origin and personal data on your physical or mental health or condition. Your consent to the use of this information does not have a specific expiration date, but you may withdraw your consent at any time by notifying the study doctor. The information shared with the Sponsor is protected by the use of a code, which is a number specifically assigned to you. The study doctor is in control of the code needed to connect your data to you.

All medical records and research materials that identify you will be held confidential so far as permitted by law. However the study doctor, the Sponsor and its representatives, Contract Research Organization (CRO), the study monitor (who checks how the study is going and makes sure that the information is being collected properly) and, under certain circumstances, the regulatory authorities and ethics committees will be able to inspect and copy confidential data that identify you by name. All personal information from this study will be treated in accordance with national and local data protection laws.

By signing this consent form, you grant permission for medical information about you obtained during this study to be made available to authorized representatives of the regulatory authorities and other government agencies. You also grant permission for this medical information to be made available to the Sponsor, Sponsor designated Contract Research Organization (CRO), the study monitor, other study personnel, and ethics committees. The Sponsor may transfer your study data to countries outside of the United States for the purposes described in this document. Please be aware that the laws in such countries may not provide the same level of data protection as in the United States and may not stop your study data from being shared with others. All data that is transferred will be coded. The study doctor, the regulatory authorities, and the Sponsor may keep the research records indefinitely.

You have the right to request information about your study data held by the study doctor and the Sponsor. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, please contact the study doctor in writing, the study doctor can help you contact the Sponsor if necessary.

If you withdraw your consent, the study doctor will no longer use your study data or share it with others. You may do this by sending written notice to your study doctor. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. The Sponsor may still use study data that were shared with the Sponsor before you withdrew your consent.

The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified by name or any other means in any of these publications.

Please see the separate supplementary form for authorization to use and disclose medical information. The supplementary form is prepared in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

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.

16. WHAT IF YOU HAVE QUESTIONS?

If you have questions about the study, or have a problem related to the study, you may contact the study doctor or his/her staff at the telephone number below.

Name: _____

Telephone: (_____) _____

If you are calling after hours or on a weekend, you may contact.

Name: _____

Telephone: (_____) _____

If you have questions about your rights as a research participant, you should contact the individual below.

(Note: Insert name of IRB/IEC chairperson and/or name of IRB/IEC, address, and telephone number.)

Name: _____

Telephone: (_____) _____

Address: _____

17. CONSENT FOR PHARMACOKINETICS* (CHECK ONE BOX):

**Pharmacokinetics (PK) sample is mandatory for the study. If you do not agree to give PK sample, you can not participate in the study.*

☐ **AGREE** to give a blood sample for mandatory pharmacokinetics (PK) research.

☐ **DO NOT AGREE** to give a blood sample for mandatory pharmacokinetics (PK) research

18. CONSENT STATEMENT OF SUBJECT

I have received verbal information on the above study and have read the above written information. I have been given the chance to discuss the study and ask questions.

I voluntarily consent to participate in this study, including all assessments, lifestyle restrictions, contraception requirements, and taking of blood and urine samples.

I understand that I am free to withdraw at any time. I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.

I agree that my primary physician may be informed of my participation in this study.

I agree that my personal data, including data relating to my physical or mental health or condition, and ethnic origin, may be used as described in this consent form.

I understand that I will receive and may keep a copy of this signed and dated consent form.

By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in a medical research study.

_____	_____	_____
Printed Name of Subject	Subject's Signature	Date

_____	_____
Signature of Legally Authorized Representative (if different from Subject)	Date

19. STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge, the subject, and or legally authorized representative, signing this consent form clearly understands the nature, risks, and benefits of participation in this research study as described in this informed consent form.

_____	_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date
_____	_____	_____
Printed Name of Witness	Signature of Witness	Date

HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The Study Doctor and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the Study Doctor and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The Study Doctor may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. The review of original medical records occurs at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), elements of dates, telephone numbers, fax numbers, social security number, medical record number, email addresses, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: elements of dates, initials and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The Study Doctor, his research team and key study site personnel associated with the research project.
- IRB (Independent Review Board)
- The study Sponsor, its business partners, affiliates, or representatives, including companies it hires to provide study related services, which includes AbGenomics B.V. and its contracted clinical research organization such as PAREXEL international.
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

- Regulatory agencies from other countries may review your study data.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. ***will expire December 31, 2060, unless you withdraw it in writing before then. (FOR CA, WA, WI, IN SITES)***

This Authorization Applicable wording from above paragraph will pull over to site-specific ICFs. INTERNAL NOTE FOR DOC GEN **HIPAA EXPIRATION WORDING BOOKMARK**

Your Study Doctor will keep this Authorization for at least 6 years.

The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

During your participation in this research project you will not be able to access that part of your medical record involved in the research. This will be done to prevent the knowledge of the research results from affecting the reliability of the project. Your information will be available to the treating physician should an emergency arise that would require for him/her to know this information to best treat you. You will have access to your medical record when the study is ended or earlier, if possible. The Study Doctor is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the use and disclosure of your PHI for this research at any time, by **writing** to the Study Doctor at the address on the first page of this form. Even if you withdraw your permission, the Study Doctor for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization will not affect the health care that is provided outside of the research study.

AUTHORIZATION TO USE AND DISCLOSE PHI

By signing this document, you are authorizing the Study Doctor to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of Subject _____ Date _____

Printed Name of Subject _____

Signature of Legally Authorized Representative (if different from Subject)	Date
Signature of Person Obtaining Authorization	Date
Printed Name of Person Obtaining Authorization	

Printed Name of Witness	Signature of Witness	Date