Master Informed Consent Form

[Investigator name]

[Investigator address or affiliation]

[Investigator telephone number]

[IRB/IEC name]

Study Title: A Randomized, Double-blind, Placebo-Controlled, Dose Escalation Study to Assess Safety, Efficacy and Pharmacokinetics of GMA301 in Subjects with Pulmonary Arterial Hypertension

Protocol Number: GETA_MAD_01

Sponsor: Gmax Biopharm LLC.

Name of Investigator or Other Person Administering Consent:

[Name of Investigator or other person]

Important

This informed consent ("permission") form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that is not clear to you.

Joining a study is an important decision. You should ask the study team any questions you may have about the study and this informed consent form before making a decision to participate.

Also, you may have your primary doctor call the study doctor to ask any questions he/she feels are necessary to evaluate the study and your possible participation in it.

You may take home an unsigned copy of this informed consent form to think about it or discuss it with family or friends before making your decision to take part in the study.

Why is this study being done?

Gmax Biopharm LLC is conducting a study of an investigational drug (also known as the "study drug") called GMA301 as a possible treatment for WHO Group 1 Pulmonary ArterialHypertension. An investigational drug is one that has not been approved by the United States (US) Food and Drug Administration (FDA). You are being invited to take part in this study because you have been diagnosed with WHO Group 1 pulmonary arterial hypertension (PAH).

PAH is a condition in which there is high pressure in the arterial vessels in the lungs. WHO Group 1 pulmonary hypertension is due to disease of the pulmonary arteries and is not due to heart failure, lung disease or blood clots. You have been asked to consider joining this study because you have been diagnosed with, and are currently being treated for PAH. GMA301 is a new drug being developed to treat PAH by blocking a receptor in the artery wall that is known to cause constriction of the pulmonary artery and result in high pressure. Unlike other oral drugs that affect this receptor (endothelin receptor antagonists or ERAs), this drug is an antibody and has very specific action on the receptor. It is hoped that it will be both more effective and safer than the other ERAs. In addition, it will be given through a vein once a month instead of on a daily basis.

Your participation in this study is voluntary. If you decide not to take part in this study, your current medical care will not be affected.

The study has received favorable/positive opinion by the Independent Ethics Committee [insert name as applicable] and an authorization from the applicable competent authorities [the Food and Drug Administration] according to the legislation in force.

How many people will take part in this study?

This study consists of 3 cohorts which are the groups of people being studied together at one time. Each of these cohorts/groups will be comprised of 12 patients, 9 of whom will receive the active study drug, GMA301 and 3 of whom will receive a placebo drug. A placebo is a medicine that looks like the actual study drug but has no medical effect. Thus, a total of approximately 36 people will be enrolled in the study in China and the United States (US). In each cohort, all 12 people will be randomly (by chance) assigned to either the active study drug (GMA301) or the placebo; in the ratio of 3:1. Neither you, the patient, nor the investigator physician or research staff at your site will know what drug you have been assigned to. This is called "blinding" and is important to judging the activity of the study drug without bias. The 3 cohorts and the treatment each will receive are described in Table 1.

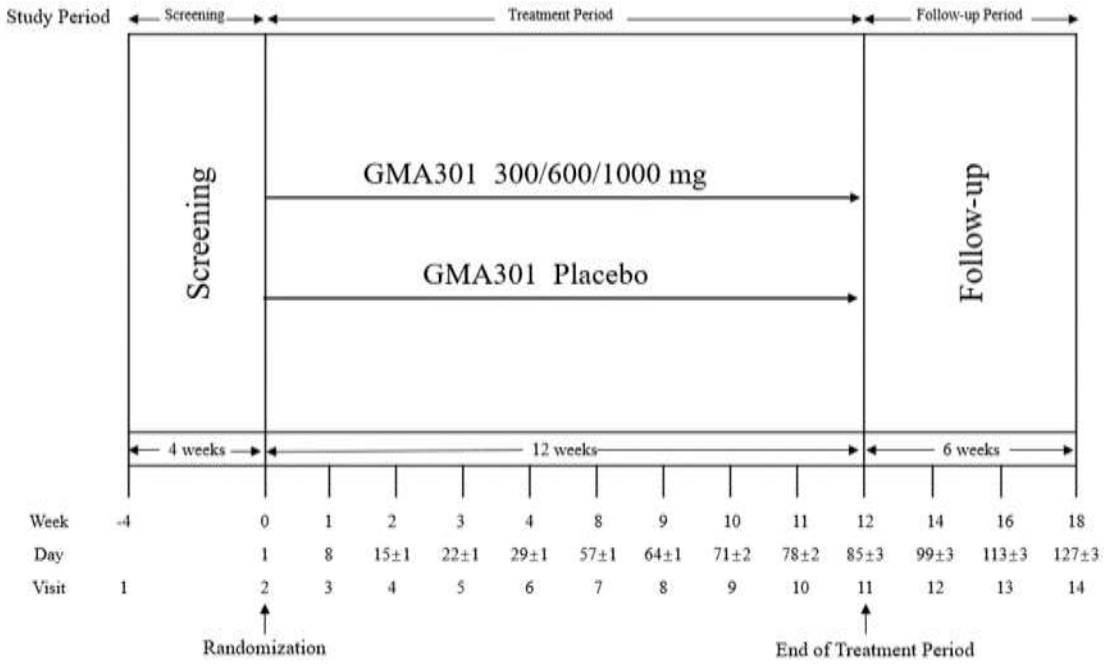
Table 1:

Cohort	Intervention	Treatment
1	GMA301 300 mg (N=9)	**Drug:** GMA301, 300 mg IV, once every four weeks , with total 3 times injection.
	Placebo (N=3)	**Drug:** Placebo, IV, once every four weeks , with total 3 times injection.
2	GMA301 600 mg (N=9)	**Drug:** GMA301, 600 mg IV, once every four weeks , with total 3 times injection.
	Placebo (N=3)	**Drug:** Placebo, ,IV, once every four weeks , with total 3 times injection.
3	GMA301 1000 mg (N=9)	**Drug:** GMA301, 1000 mg IV, once every four weeks , with total 3 times injection.
	Placebo (N=3)	**Drug:** Placebo, IV, once every four weeks , with total 3 times injection.

You will participate in any one cohort of the study.

How long will my participation in this study last?

Your participation in this study will last up to 22 weeks. Your visits to the research site are scheduled as following schema.



What will happen during this study?

During this study, there are Screening visits, a Baseline visit, 9 Treatment visits (every 4 weeks) when you will receive the study drug injections, and 4 follow-up visits.

During each study period, you will have 1 or more visits to the study doctor at the center. The Screening and Treatment visits may last about 3 to 4 hours, and other visits may last about 1 to 2 hours.

Before any study-related tests, procedures and treatment changes can be done, you will be asked to read and sign this informed consent form. After you sign this informed consent form, the study will begin with a screening visit. The purpose of the Screening Visits are to determine if you meet the requirements to take part in this study and to measure your baseline state of health before receiving study drug treatment. If you do not meet the requirements for study entry, the study doctor will explain why and will discuss with you other treatment options. Your medical care will not be effected if you decide not to participate in this research trial.

Study Procedures and Assessments

This is a description of the procedures and assessments that will be performed during the study, including the screening visits, shown below. In addition to the visits described below, the study doctor may ask you to come in for extra visits, if necessary, for your safety.

Table 2: Schedule of Assessment

	Screening [a]	Randomization [b]	Treatment period									Follow-up			
Week	**-4**	**Day -1**	**0** [c]	**1**	**2**	**3**	**4**	**8**	**9**	**10**	**11**	**12** [d]	**14**	**16**	**18**
Day (range)		**-1**	**1**	**8**	**15±1**	**22±1**	**29±1**	**57±1**	**64±1**	**71±2**	**78±2**	**85±3**	**99±3**	**113±3**	**127±3**
Visit	**1**	**2**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Informed consent	×														
Inclusion/exclusion criteria	×														
Demographic data	×	×													
Medical history	×	×													
Concomitant medication	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Vital signs	×	×					×	×				×			
Height	×														
Body weight	×	×					×	×				×			
Physical examination	×	×					×	×				×			
Serology tests [e]	×														

	Screening [a]	Randomization [b]	Treatment period									Follow-up			
Week	**-4**	**Day -1**	**0 [c]**	**1**	**2**	**3**	**4**	**8**	**9**	**10**	**11**	**12 [d]**	**14**	**16**	**18**
Day (range)		**-1**	**1**	**8**	**15±1**	**22±1**	**29±1**	**57±1**	**64±1**	**71±2**	**78±2**	**85±3**	**99±3**	**113±3**	**127±3**
Visit	**1**	**2**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Hematology, clinical chemistry, and coagulation	×	×					×	×				×			
Urinalysis	×	×					×	×				×			
Pregnancy test [f]	×	×					×	×				×			
FSH [g]	×														
Pulmonary function	×											×			
Injection of GMA301 or placebo			×				×	×							
Pharmacokinetics sampling			×	×	×	×	×	×	×	×	×	×	×	×	×
Immunogenicity (ADA) [h]			×		×		×	×				×			×
NT-proBNP		×					×	×				×			
AE recording	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
12-lead ECG	×	×					×	×				×			

	Screening [a]	Randomization [b]	Treatment period									Follow-up			
Week	**-4**	**Day -1**	**0** [c]	**1**	**2**	**3**	**4**	**8**	**9**	**10**	**11**	**12** [d]	**14**	**16**	**18**
Day (range)		**-1**	**1**	**8**	**15±1**	**22±1**	**29±1**	**57±1**	**64±1**	**71±2**	**78±2**	**85±3**	**99±3**	**113±3**	**127±3**
Visit	**1**	**2**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
RHC	×											×			
Echocardiogram	×							×				×			
6MWT (Borg dyspnea scale)	×											×			
WHO function classification	×	×						×				×			
REVEAL risk score		×										×			

Abbreviations: 6MWT = six-minute walk test; ADA = Anti-drug antibodies; ECG = electrocardiogram; FSH= follicle stimulating hormone; RHC = right heart catheterization.

a. Screening period will be up to 4 weeks. If a Screening test was performed within 3 days prior to Week 0, the results can be used as baseline (Week 0) results. No need to repeat the test at Week 0.
b. Day -1 the randomization day can also be the first day of Week 0, ie, the baseline blood sampling and information collection can be conducted just before the first dosing.
c. The samples at Week 0 will be collected on Day 1 of Week 0 before the first dosing.
d. Tests can also be done on the last day of Week 11. If a subject discontinues the visit in advance, it would be better to ask the subject to complete the Week 12 examinations.
e. Serology tests refer to Hepatitis B surface antigen, Hepatitis C antibody, and Human Immunodeficiency Virus antibodies.
f. Women of childbearing potential will perform pregnancy test in serum at Screening and in urine at randomization and Weeks 4, 8, and 12.
g. FSH test will be performed at the same time with serum pregnancy test at Screening.
h. ADA will be collected at: Week 0 (predose of the 1st dose), Week 2, Week 4 (prior to 2nd dose), Week 8 (prior to 3rd dose), Week 12 and Week 18 (end of follow-up).

Initial Screening Visit

The study doctor will perform the following examinations and tests to determine if you should take part in the study:

1. You will be asked about your health and the medicines that you have taken or are currently taking, and the medical procedures that you have had.
2. You will be asked about your diagnosis and treatment history.
3. Your birth date, sex, and race, per national regulations, will be recorded.
4. You will be assessed for your disease-related signs and symptoms.
5. The study doctor will perform a physical examination to check your overall health, including height and weight.
6. Your blood pressure, pulse rate, respiratory rate, and body temperature will be measured.
7. An electrocardiogram (ECG) will be done. This is a test that measures the electrical activity of the heart. A technician will place patches on your chest that will be connected by wires to a machine. The machine will record the electrical activity of your heart.
8. An Echocardiogram (ECHO) this is a test that uses high frequency sound waves (ultrasound) to make pictures of your heart.
9. A urine sample (about ½ cup) will be taken to check your overall health.
10. Right heart catheterization and six-minute walk test will be done.
11. Pulmonary function test will be done.
12. Blood samples will be collected for the following laboratory tests. Approximately 3-4 teaspoons or 15-20 mL of blood will be taken from your arm using a needle during each study visit.
    - Safety laboratory tests will be done to check your overall health.
    - If you are a woman who is able to have children, your blood will be tested to see if you are pregnant. The results of the pregnancy test must be negative in order for you to participate in this study.
    - If you are postmenopausal (not had a menstrual period for at least 12 months). Your FSH hormone (Follicle-stimulating hormone) level will be measured to confirm your postmenopausal status)
    - Tests will be done to screen for certain viruses (including human immunodeficiency virus and hepatitis B and C viruses). If your test result is positive and you have given or received blood, blood products, organs or tissues, the Public Health Department will be notified as required by law. These tests are mandatory. If you decline these tests, you will not be allowed to participate in the study.
13. The study doctor will review any side effects you experienced after you sign on this informed consent form.

Treatment Period

The study doctor or the study doctor's staff will perform the following tests and procedures. You will be asked to visit the study site as shown in the schema. The study staff will explain to you in detail about study site visits.

1. Your eligibility criteria will be reviewed at Baseline.
2. You will be asked about your diagnosis and treatment history.
3. You will be assessed for your disease-related signs and symptoms.
4. You will be asked about your health and the medicines that you have taken or are currently taking, and the medical procedures that you have had.
5. The study doctor will perform a physical examination to check your overall health and weight by symptom driven. Also, the study doctor will examine you, if clinically indicated.
6. Your blood pressure, pulse rate, respiratory rate, and body temperature will be measured.
7. If you are a woman who is able to have children, your urine will be tested to see if you are pregnant (before every dose, about every 4 weeks).
8. Study drug should be administered according to dose schedule.
9. ECG will be done at at week 4, week 8 and week 12.
10. ECHO should be measured at week 8 and week 12.
11. A urine sample (about 1/2 cup) will be taken to check your overall health (may not be performed at Baseline visit, at your doctor's discretion).
12. Blood samples will be collected for the following laboratory tests. Approximately 1-2 teaspoons or 5-10 mL of blood will be taken from your arm using a needle.
    - Safety laboratory tests will be done to check your overall health (may not be performed at Baseline visit, at your doctor's discretion).
13. The following blood tests will be performed as **Table 2**:
    - Pharmacokinetic (PK) tests will be done to look at how your body metabolizes (breaks down) the study drug. The blood samples will be taken before and after the study drug administration.
    - Anti-drug antibody (ADA) tests will be done to check if there is any anti GMA301 antibodies in your body.
    - Biomarkers (NT-pro-BNP) tests will be done to evaluate the efficacy of the treatment.
14. Review of side effects experienced since your previous study visit.

Early Discontinuation Visit

If you leave the study before study completion and leave earlier than week 12 especially, the study doctor will schedule a visit to perform the following tests and procedures:

1. You will be asked about your diagnosis and treatment history.
2. You will be assessed for your disease-related signs and symptoms.
3. You will be asked about your health and the medicines that you have taken or are currently taking, and the medical procedures that you have had.
4. The study doctor will perform a physical examination to check your overall health, including weight.
5. Your blood pressure, pulse rate, respiratory rate, and body temperature will be measured.
6. Right heart catheterization and six-minute walk test will be done
7. A urine sample (about 1/2 cup) will be taken to check your overall health based on your doctor's decision. .
8. If you are a woman who is able to have children, your urine will be tested to see if you are pregnant.
9. ECG will be done.
10. ECHO will be measured
11. Blood samples will be collected for the following laboratory tests. Approximately 1-2 teaspoons or 5-10 mL of blood will be taken from your arm using a needle.
    - Safety laboratory tests will be done to check your overall health.
12. Review of side effects experienced since your previous study visit.

Follow-Up Period

Follow-Up Visit

A safety follow-up visit will be scheduled as the schema. At these visits, the study doctor or the study doctor's staff will perform the following tests and procedures:

1. You will be asked about the medicines that you have taken or are currently taking.
2. The study doctor will perform a physical examination to check your overall health, including weight.
3. Review of side effects experienced since your previous study visit.
4. You will be asked about the new treatment for your disease. i.e. your present health.
5. If you are a woman who is able to have children, your urine will be tested to see if you are pregnant.
6. PK blood samples will be collected at week 14,16 and 18.

7. ADA blood samples will be collected at week 12 and 18
8. Right heart catheterization, six-minute walk test, ECG, ECHO, Safety laboratory tests and biomarker tests will be done at week 12.

What do I have to do?

During the study, you will have the following responsibilities:

- Tell your study doctor if you have any allergies, including drug allergies. If you are unsure, ask your primary doctor.
- Attend all scheduled visits.
- Follow the study doctor's instructions about whether you may continue to take your regular prescribed medications or over-the-counter medicines during the study period.
- Tell the study doctor of any changes to your current medications, illnesses or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.
- You should not perform activities requiring mental alertness, judgment, or physical coordination such as driving or operating machinery, or doing anything that requires you to be alert, unless you feel secure and safe to do so.
- You should continue to make regular visits to your primary doctor or any other special doctors whom you were seeing before starting the study, because being in the study does not replace regular medical care.
- Contact the study doctor if you find you have any questions about the study after you sign this form.
- You and/or your partner must use a reliable form of contraception during the study and until 90 days after you finish the study treatment. If you or your partner becomes pregnant while you are in the study, be sure to tell the study doctor as soon as possible.

What are the benefits of being in this study?

There is no guarantee that you will receive any benefits from this study. However,taking part in this study will help doctors to learn more about the study drug. This may help others with your health problem in the future..

What are the risks and possible discomforts?

If you choose to take part in this study, there are risks that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions which you normally do not discuss.

The drug used in this study might affect the function of other organs, such as liver, kidneys, heart and blood. The study doctor will be testing your blood and will inform you if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug and the study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects might be serious and may even result in death.
- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

The previous study on the GMA301 in human has shown that its safety profile is acceptable. The common side effects are headache, nausea and pharingitis. There might be other side effects that researchers do not yet know. The other possible common or severe side effects seen in a drug in the same class approved by FDA are listed in Table 3. Additionally, all therapeutic monoclonal antibodies, including GMA301, have the potential to cause injection reactions with common symptoms of fever/chills, nausea, vomiting diarrhea, itching/flushing, rash, changes in blood pressure and heart rate, dyspnea, chest discomfort back and abdominal pain. Injection site reactions could occur, with symptoms of redness, itching, pain, swelling, bruising, burning, or a small amount of blood loss.

Table 3: Potential Sides Effects

Common Side Effects	Peripheral edema, Dyspepsia, Oligospermia, Decreased haemoglobin, anemia, decreased haematocrit, Nasal congestion, bronchitis, sinusitis, fatigue, fluid retention, hypersensitivity, hypotension, increased liver enzymes, vomiting, weakness
Potentially Severe Side Effects	Cardiac failure, it may cause fetal harm, dizziness

Let your study doctor know of any questions you have about possible side effects.

Pregnancy/Birth Control

Because the effect of GMA301 on unborn babies is not known, however, drugs that are similar to GMA301 are identified as agents that could cause malformation of babies, you should not become pregnant, breastfeed or father a baby while in this study. Therefore, if GMA301 is used during pregnancy, or if the patient becomes pregnant while on GMA301, please be aware of the potential hazard to a fetus and talk with the study doctor right away.

Women

Taking the study drug may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby), or breastfeeding infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot take part in this study.

Before entering the study, a pregnancy test will be done for women of childbearing potential. This test might not detect an early pregnancy. Pregnancy tests will be repeated during the study.

The only certain way not to become pregnant is to not have sex. If you choose to have sex during the study, you must use an effective method of birth control while you are taking part in this study and for 90 days after you finish the study treatment. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable for use during this study. Methods of effective birth control include surgery, hormonal contraceptive, patch, vaginal ring, intrauterine device, or double physical barrier such as condoms plus diaphragm.

If during the study you become pregnant, you should tell the study doctor as soon as possible. The study drug will be stopped, and your involvement in this study will end.

Men

Male subjects whose partners could be of child bearing potential should be surgically sterile or compliant with a highly effective contraceptive method during the study and for 90 days after you finish the study treatment. These may include surgery or a physical barrier such as a condom. Their partner should also use effective birth control methods; such as surgery, hormonal contraceptive, patch, vaginal ring, intrauterine device, or double physical barrier such as condoms plus diaphragm; for the same period of time.

The Sponsor may like to receive updates on the progress of the pregnancy and its outcome.

What if there are new findings?

If new findings that would affect your safety and willingness to participate in the study are identified while you are in the study, you will be told as soon as possible, so you can decide

whether to leave the study or continue. If you continue, you will be required to sign a new informed consent form.

What other options are available if I do not take part in this study?

You do not have to take part in the study to treat your disease. There are other options of therapies, such as blood vessel dilators (vasodilators), Sildenafil and tadalafil, High-dose calcium channel blockers, Soluble guanylate cyclase (SGC) stimulator, and surgeries.

Your primary doctor or the study doctor can answer any questions that you have about other treatments.

You should also contact your primary doctor to ask about other research currently being done in the treatment of WHO Group-1 Pulmonary Arterial Hypertension.

Who is paying for this study?

Gmax Biopharm LLC is funding this study. The study doctor will be paid for his/her work in this study.

What are the costs?

The study drug will be given at no cost to you, and you will not be charged for any study doctor visits, laboratory work, tests, or procedures that are needed for the study.

Will I be paid for being in the study?

You will not receive any payment for taking part in this study. However you may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit, upon approval from the Sponsor.

What if I get sick or hurt?

If you require medical treatment for an illness or injury that is a direct result of taking the study drug, Gmax Biopharm LLC will pay for reasonable and routine costs of such treatments if the following conditions are met:

- The illness or injury was a result of taking part in the study.

- The cost of treatment or any part of the costs is not covered by any other health insurance, government health program, or other institutions providing coverage for health care.

Can I leave the study after it has begun?

Yes. Taking part in this study is voluntary, and you can leave the study at any time for any reason. There will also not be any penalty or loss of benefits to which you are entitled at this site if you decide not to take part or if you decide to leave the study.

If you decide to leave the study, you should contact the study doctor who will explain the safest way to end participation, which may involve the completion of some final tests and examinations. You should also contact your primary doctor so he or she can provide you with the best course of continuing care.

If you withdraw your consent, no new information or biological samples will be taken from you. The data already obtained at the time of consent withdrawal from previous testing on samples will continue to be kept only in an anonymized form. You may ask to delete your data and destroy your samples; however, this request is subject to certain exceptions and will be assessed as necessary to comply with applicable legal or regulatory requirements; or as necessary to maintain the integrity of the study.

The study doctor or Gmax Biopharm LLC can remove you from the study, without your permission, for any reason. Possible reasons for doing so include the following:

- Any change in your medical condition that might make continuation in the study harmful to you
- Your failure to follow the study doctor's instructions
- Discovery that you do not meet the study requirements
- Cancellation of the study
- Administrative purposes: For example, insufficient drug supply or site closing etc.

What will happen to the samples that I provide?

Your samples will be used for the research purposes explained in the procedures section of this form. Your samples will be coded to protect your identity and will be identified by your subject identification number.

The blood samples that you give will be used only for specific tests that are needed for this study and will be destroyed as soon as possible after those specific tests are completed according to the standard procedures of the laboratory. Your samples will not be sold or used directly for the production of commercial products.

In case of any commercial gain based on the research results from your samples, the sponsor will have the ownership of the research results and may file patents. The research done with your samples may help to develop new products, new medical tests or treatments in the future that have commercial value. There will be no financial benefit to you for any commercial findings or products as a result of your sample use.

What happens when this study stops?

When the study stops, you will be under the care of your primary doctor who will decide the best way to treat your disease. The study drug will no longer be available to you.

You have the right to be informed of the overall results of the study.

Will my records be kept private?

To participate in this study, you must read and sign the Privacy Notice at the end of this form (see Appendix 1).

What if I have a question or concern?

You should feel free to ask questions about the study and your rights as a subject before, during, and after the study.

Whom can I call?

If you have any questions about this study or if at any time you believe that you have a research-related injury or a reaction to the study drug, you should contact *<insert study doctor's name>* by telephone at at *<insert his/her telephone number>*.

If you have any questions regarding your rights as a research subject, you may contact *<insert IRB/IEC name>* by telephone at *<insert IRB/IEC telephone number>*..

Important

Do not sign this informed consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Signing your name to this informed consent form means that you voluntarily agree to take part in this study.

This agreement can be withdrawn at any time; although, data collected up to that point is legally allowed to be used.

Consent to Participate

By signing this informed consent form, I agree to the following:

- I have read, and I understand this informed consent form.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand the risks of taking part in this study as described in this informed consent form.
- I understand that there is no guarantee that I will receive any benefits from taking part in this study.
- I freely consent to be treated with drug under the study doctor's care.
- I confirm that all information that I have given about my medical history is correct to the best of my knowledge.
- I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner, and my future care can be discussed.
- I understand that I will be told of any new information that might relate to my willingness to continue in the study.
- I will tell the study doctor if I have any physical or psychiatric ("mental health") symptoms or problems.
- I understand that I will receive a signed and dated copy of this informed consent form for my records.

My consent to participate in this study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study.

_____

Name of participant (print)

_____ _____

Signature of participant Date (MM/DD/YYYY)

_____ _____

Signature of study doctor or person obtaining consent Date (MM/DD/YYYY)

Appendix 1: Privacy Notice

Identification of Data Controller: During the study, the Sponsor will direct the collection and use of your personal information (data) needed for the study. The Sponsor is the data controller of your personal data under applicable data protection laws. You can contact the Sponsor at:

Quanyu Su
Gmax Biopharm LLC.
address Room 302, Building No. 2, 288 Qiuyi Road
Binjiang District, Hangzhou, 310052, China
Tel: + 86-571-86633901

The study center may also be considered as a data controller of your personal data under applicable data protection laws. You may contact the study doctor using the contact information for the study doctor on the first page of this informed consent form.

If you have any questions or would like to see the data collected about you for this study, you should contact the study doctor.

Data to be Collected and Processed: The study staff will collect data about you for the study. This data may include your name or initials, date of birth, gender, contact details, and information needed for payment processing. In addition, the following sensitive personal data about you may be collected: health, race, genetic information.

How Your Personal Data Will be Used: The personal data collected about you will be recorded in your study file by the study staff to run the study and to monitor your safety as a participant. Your personal data may be processed on a computer and/or on paper. The collection of this data is necessary to conduct the study and comply with applicable laws. You will not be able to participate in the study if you fail or refuse to provide your information.

There are laws about the recording, forwarding, storage, and analysis of your personal data, including sensitive personal data. These laws require your voluntary and explicit consent before you participate in the study. If you do not consent to the collection and use of your personal information, you will not be able to be in the study.

Results of this study may be presented at meetings or in publications; however, your identity will never be shared. Your personal data will not be used for any direct marketing purposes.

If information regarding a communicable disease is collected, the information may be shared with a public health authority that is authorized by law to collect or receive such information for

the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Storage of Your Personal Data: According to legal requirements, your personal data will be stored in the study databases and/or paper files for whichever period is longer, as required by applicable laws:

- at least 15 years after the study ends

Transferring the Personal Data to a Third Party: To keep your identity private, all data that is sent or provided outside of the study center will show only a coded identification number instead of your name. Only the study doctor and authorized personnel will be able to connect this code to your name. They will use a list that will be kept in a secure place to link this code to your name in case of an emergency. The coded data from the study showing your involvement (including uncoded personal information) will be provided to the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Covance. Also, your medical records (including uncoded personal data) may be reviewed by the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Covance; government agencies in countries where the study drug may be considered for approval (such as the US FDA); [IRB/IEC name], a group that reviews and approves studies; and independent auditors for the purposes of confirming your participation in the study, monitoring your safety during the study, and monitoring the conduct of the study. Further, your personal information may be disclosed in response to lawful requests by public authorities, including those to meet national security or law enforcement requirements.

If your personal data is shared with other companies that are located outside of the country where you live, the Sponsor will make sure your data is protected as required by your country's data protection laws. Some of these other companies may be located in countries whose data protection and privacy laws may be less strict than in your own country, including the United States and The People's Republic of China. You may contact the study doctor to get more information about the precautions used to protect your personal data outside of your country. You may also ask the study doctor for a copy of those precautions.

With your permission, the study doctor will tell your primary doctor about your role in this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by US 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.

Your Rights as a Data Subject: You have the right to access and correct the data collected about you during the study and submit any questions or concerns about the collection or

processing of your personal data, however this access is suspended until after the study has ended Your rights will be reinstated at the conclusion of the study.

You have the right to withdraw your consent for the processing of your personal data at any time. You must withdraw your consent by writing to the study doctor. However, data collected before you remove your consent is still legally allowed to be used. If you withdraw your consent, you will no longer be able to take part in the study.

Consent Language

Consent to the Collection, Processing, and Use of Personal Data

By signing below, I agree that:

(1) My personal data, including sensitive personal data, can be collected, used, and archived for purposes of carrying out the study as described in this Privacy Notice;

(2) My personal data, including sensitive personal data, can be transferred to and shared with other companies both within and outside of the European Economic Area (EEA), including to countries that may not have the same level of data protection as the EEA, as described in the Privacy Notice;

This consent is valid unless you change your mind and provide a written notice to the study doctor. You will receive a signed and dated copy of this Privacy Notice.

_____

Name of participant (print)

_____ _____

Signature of participant Date (MM/DD/YYYY)