INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Artiva Biotherapeutics, Inc. / "A Phase 1 Study to Evaluate the Efficacy and Safety Of AB-101, an Allogeneic Cord Blood Derived NK-Cell Therapy in Combination With B-Cell Depleting mAb, in Patients Who Failed Treatment for Class III or IV Lupus Nephritis or other forms of refractory Systemic Lupus Erythematosus"**
Sponsor Address:	**5505 Morehouse Drive, Suite 100 San Diego, CA 92121**
Protocol Number:	**AB-101-03**
Principal Investigator: (Study Doctor)	**C. Kent Kwoh, MD**
Telephone:	**520-626-8750 (520) 694-6000 (24 Hours)**
Address:	**University of Arizona Arthritis Center 1501 North Campbell Avenue Room 8303 Tucson, AZ 85724**

INTRODUCTION

You are being asked to take part in a research study of an experimental cell therapy product called AB-101. Your participation in this study is voluntary. You do not have to take part in this study if you do not want to. Before you decide to take part, we would like you to understand why the research is being done and what it would involve for you. **One of the research team members will go through this information with you and answer any questions you have. Please take your time to make your decision. Talk to others (for example, your family or friends) about the study, if you wish.**

The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

SUMMARY AND PURPOSE OF THE STUDY

The main purposes of this study are to see whether AB-101, an investigational cell therapy product, is safe when given to subjects with lupus nephritis or systemic lupus erythematosus, and to see whether subjects have an improvement of their lupus after receiving AB-101. "Investigational" means that AB-101 has been approved by neither the United States Food and Drug Administration (FDA) nor any other regulatory agency, and it is only available to people who are participating in research studies.

You are invited to take part in this study because you have lupus nephritis or systemic lupus erythematosus that has stopped responding to FDA-approved treatments.

In this study, AB-101 is given as an infusion into a vein (also called an "IV [intravenous] infusion"). AB-101 is made from NK (or "natural killer") cells obtained from human umbilical cord blood. Natural killer (NK) cells are a type of white blood cell that can kill cancer cells and virus-infected cells. They are part of the immune system and help protect the body from harmful invaders. In addition, NK cells in combination with rituximab or obinutuzumab may deplete defective B-lymphocyte cells that are responsible for making antibodies against your normal body tissue and cause your lupus nephritis or systemic lupus erythematosus. The NK cells in AB-101 are obtained from the umbilical cords of healthy newborns after birth and are regulated by the FDA for this purpose.

If you choose to participate in this study, you will first have a series of tests and assessments done to see whether you meet all the requirements for study entry – this is called the "Screening period". If you meet all the requirements for the study, you will be assigned to a study treatment group and will proceed to the next part of the study called the "Study Treatment Period". After the Study Treatment period is over, then you will have a series of follow-up visits called the "Follow-Up Period".

There are nine (9) study treatment groups or cohorts in this study, and you will be assigned to only 1 of these groups. In these groups or cohorts, AB-101 is given by itself in Cohort 1 (i.e., as monotherapy), or it is given in combination with rituximab or with obinutuzumab at three possible dose levels. Based on the results from the combination of AB-101 with rituximab or obinutuzumab, four (4) cohorts may be selected for further study in an expansion group, where additional subjects will be enrolled to be tested. The specific study treatments you will be given will depend on the group to which you are assigned, as listed below. All study drugs, aside from AB-101 that are given in this study are FDA-approved, but the dose or the administration schedule of these agents may not follow the FDA's approved use. All study treatments must therefore be considered as experimental.

Study Treatment Name	Purpose for Use	Route of Administration	Potential Risks
AB-101	Experimental use to study if this product can reduce the	IV Infusion	AB-101 has been shown to be safe and well tolerated in an ongoing cancer study, but similar cell therapies have

Study Treatment Name	Purpose for Use	Route of Administration	Potential Risks
	defective B-lymphocyte cells that cause lupus		reported cytokine release syndrome (CRS) and neurotoxicity. Refer to the Risks and Discomfort section for more details.
Cyclophosphamide	Approved for use in lupus treatment to reduce white blood cell count. This use may also support the health and activity of AB-101 cells in your body (lymphodepletion)	IV Infusion	Cyclophosphamide reduces white cell count and that can make subjects more susceptible to infection, bleeding, or anemia. Refer to the Risks and Discomfort section for more details.
Fludarabine	Not approved for use in lupus treatment, but will reduce white blood cell count to support the health and activity of AB-101 cells in your body (lymphodepletion)	IV Infusion	Fludarabine reduces white cell count and that can make subjects more susceptible to infection, bleeding, or anemia. Refer to the Risks and Discomfort section for more details.
Rituximab	Not approved, but often used for lupus treatment. This monoclonal antibody may help AB-101 target defective B-lymphocytes in your body	IV Infusion	Rituximab may cause flu-like symptoms, headache, fever, chills, infections, stomach pain, nausea, diarrhea, heartburn, flushing, night sweats, weakness, muscle or joint pain, back pain, and dizziness. Severe allergic reactions have also been observed. Refer to the Risks and Discomfort section for more details.
Obinutuzumab	Not approved, but studied for lupus treatment. This monoclonal antibody may help AB-101 target defective B-	IV Infusion	Obinutuzumab may cause flu-like symptoms, headache, fever, chills, infections, stomach pain, nausea, diarrhea, heartburn, flushing, night sweats, weakness, muscle or joint pain, back pain, and dizziness. Severe

Study Treatment Name	Purpose for Use	Route of Administration	Potential Risks
	lymphocytes in your body		allergic reactions have also been observed. Refer to the Risks and Discomfort section for more details.

Taking part in any research study involves risks and may provide some benefits. It is important to understand these risks and potential benefits to make an informed decision about whether you wish to be in this study. Risks are described in the RISKS AND DISCOMFORTS section of this consent form.

NUMBER OF SUBJECTS AND LENGTH OF STUDY

The study will last approximately three (3) years. About 42 subjects will be included in this study, participating from up to 30 clinical centers.

Abbreviations: FU=Follow up visit; EOT=End of treatment visit; EOS=End of study visit

For all subjects in this study, the Screening period can last up to 28 days. If you are eligible to enter the study, then you will begin the Study Treatment Period. Your study treatment will take place over 4 weeks, which will be one cycle of study treatment. Your total study treatment will consist of up to 2 cycles approximately 6 months apart.

If you were assigned to receive AB-101 by itself (i.e., as monotherapy) in the first study treatment cycle, then you may be offered AB-101 in combination with rituximab or obinutuzumab for your second cycle following six months after your first cycle if your study doctor considers it safe, your lupus nephritis or systemic lupus erythematosus has not worsened, and if you agree. If your monotherapy study treatment results in a complete response in your lupus nephritis or a significant improvement in your systemic lupus erythematosus, then your study doctor may decide to withhold further study treatment and just observe you, or your study doctor may decide to administer rituximab or obinutuzumab alone without additional lymphodepletion or AB-101.

If you were assigned to receive AB-101 in combination with rituximab or obinutuzumab in the first study treatment cycle and you tolerate this study treatment cycle well, your lupus nephritis or systemic lupus erythematosus has not resolved, and if you agree, then you may be eligible to receive a second study treatment cycle following six months after your first study treatment cycle. This second cycle of study treatment will be identical to the first cycle, including lymphodepletion, AB-101 and rituximab or obinutuzumab. If your first AB-101 combination study treatment cycle results in a complete response in your lupus nephritis or a significant improvement in your systemic lupus erythematosus, then your study doctor will only administer rituximab or obinutuzumab alone without additional lymphodepletion or AB-101.

After the Study Treatment period has concluded, you will enter the Follow-Up period, which will consist of regular visits with your study doctor every 6 to 12 weeks, and then less frequently after

the first year. Unless you choose to withdraw or are withdrawn from the study, your involvement in the study will last until you have completed all required follow-up visits, which will be about 24 months after you enter the Study Treatment period, no matter which group or cohort you have been assigned to.

STUDY PROCEDURES

SCREENING PERIOD:

To determine if you can safely participate in this study, your study doctor will evaluate your medical history, perform a physical examination, and request several tests, including blood and urine tests, a specialized heart exam such as an echocardiogram (ECHO) or MUGA (multi-gated acquisition scan), and a 12-lead electrocardiogram (EKG), and specialized tests to assess your lung function. If you are female and can conceive a child, you will be asked to take a blood or urine test to make sure you are not pregnant. You must have had a kidney biopsy within the last six months to qualify for this study. If needed, a biopsy may be scheduled during this screening period, and you will sign a separate informed consent form for that procedure.

The need for COVID-19 testing will be decided by your study doctor and will follow the policies of the treatment clinic. If you have a positive test result or otherwise have symptoms of COVID-19, please let your study doctor know immediately. Your study doctor may delay or discontinue study treatment for your safety.

If you are found to be eligible to participate in this study after all required screening assessments are completed, then you will be enrolled and will enter the Study Treatment Period.

STUDY TREATMENT AND FOLLOW-UP PERIODS:

For safety observations, you will be admitted to the hospital for your first infusion of AB-101 if you are the first subject to be enrolled to a study treatment group or cohort. Unless hospital admission is required by your study treatment center, all other study treatments will be given in the outpatient setting, which means that you will not need to spend the night at the hospital.

All subjects will start the first cycle of study treatment with lymphodepleting chemotherapy, which is three consecutive days (Days 1-3) of fludarabine and one day (Day 3) of cyclophosphamide administered by IV infusion, followed by two days of rest with no study treatment. On each of these days, before chemotherapy, your study doctor will confirm that it is safe to proceed by examining you, asking you questions about your health, and performing several tests, including pulse oximetry (to measure the level of oxygen in your blood) and blood and urine tests. You will have a 12-lead EKG on the first day of chemotherapy only. If you are a female of childbearing potential, you will also have a pregnancy test done on the first day of chemotherapy and several more times throughout the study. Lymphodepleting chemotherapy will be administered with the second cycle of study treatment if your study doctor considers it safe, your lupus nephritis or systemic lupus erythematosus has not improved, and if you agree. You will not receive chemotherapy in your second study treatment cycle if your lupus nephritis shows a complete response, or there is significant improvement in your systemic lupus erythematosus following the first study treatment cycle.

Unless you have been assigned to receive AB-101 as monotherapy only during the study treatment cycle, you will also receive rituximab or obinutuzumab by IV infusion on Day 2 and Day 13 of the first study treatment cycle, and on Day 1 and Day 15 of the second study treatment cycle.

If you are scheduled to receive AB-101 during a study treatment cycle, this will be dosed by IV infusion one week apart, on Day 6, Day 13, and Day 20 of the study treatment cycle. Depending on how your lupus nephritis or systemic lupus erythematosus has responded to the first study treatment cycle, the second study treatment cycle may or may not include AB-101 doses.

Before receiving each dose of AB-101, your study doctor will confirm that it is safe to proceed by performing several tests, including taking a small amount of blood for testing. You will be given a Tylenol® tablet with or without an antihistamine tablet or injection (like Benadryl®) to reduce the likelihood of a reaction to your study drugs about 30 minutes before each AB-101 dose. For your safety, you will be monitored closely for at least four hours after your first AB-101 dose. If you tolerate the first dose with no problems, then you will only be closely observed for at least one hour following your subsequent doses.

About a week after your last AB-101 dose in each cycle (on Day 28), you will have another visit where your study doctor will examine you and ask you questions about your health and wellbeing and if there have been any changes in the medications you are taking. You will have several tests performed, including taking a small amount of blood and urine for testing. Depending on what cycle you are in, you may also have several other tests performed, like a 12-lead EKG.

You will have a visit called the End of Study Treatment (EOT) visit about 30 days after your last dose of study treatment, where your study doctor will examine you and ask you questions about your health and wellbeing and if there have been any changes to your medications. You will have several tests performed, including pulse oximetry, a 12-lead EKG, an ECHO or MUGA.

After that, you will enter the Follow-up Period and will have study visits every 6-12 weeks. You will continue to have blood and urine tests done at these visits, and your study doctor will also examine you and ask you questions about your health and wellbeing, and about any changes in medications or lupus treatments that you may have gotten since the last visit. Your last study visit will be about 24 months after you start the study treatment period.

UNSCHEDULED VISITS

Regardless of the group or cohort that you are assigned to, you may be asked to come into clinic for an additional study visit if your study doctor believes you need to be evaluated at a time other than the visits listed above. Information about these visits would be collected as part of the study. Any of the assessments listed above may be performed, as your study doctor thinks is necessary.

RESEARCH RELATED TESTING

You will have samples drawn for both research and safety testing while you are in this study. The total amount of blood taken for research testing over the full course of the study (up to 24 months total) will be approximately 515 mL (a little more than 2 1/6 cups). For comparison, a standard blood donation collects about 450 mL of blood, all taken at one time (a little less than 2 cups).

It may be necessary to take more blood samples during the study to follow up on your safety. The study staff will explain when and why these extra tests are needed before collecting these extra samples.

None of the research-related testing results will affect your care or your participation in this study. The research-related results will not be placed in your medical records and will not be available to you or to your study doctor. Neither you nor your health insurance provider will be charged for the cost of any research sample processing, storage, and testing.

Any leftover blood or tissue samples may be provided to the Sponsor and other researchers and may be stored for re-testing or for future use or testing. This may include testing or use in research related to how AB-101 works. The samples may also be used or tested to learn about, prevent, or treat other health-related problems, and some of this research may include limited genetic testing. Information obtained from testing the samples will be used only for research purposes and will not provide information for making health care decisions.

These samples will be transferred to the Sponsor or their contracted laboratory for long-term storage. Only your study-assigned subject number and the date and time of the sample collection will be kept with the samples. The testing labs will not have access to any other information about you.

RISKS AND DISCOMFORTS

The combination of AB-101 with rituximab has been studied in over 20 subjects with Non-Hodgkins Lymphoma, a type of cancer of the lymphatic system, and this combination has been considered safe and well tolerated, even at AB-101 doses higher than planned for this study. This is, however, the first study of AB-101 in combination with rituximab in subjects with lupus nephritis or systemic lupus erythematosus, and taking part in this study involves some risks and possible discomforts. The combination of AB-101 with obinutuzumab has not been studied in clinical trials, and the safety of administering this combination to subjects is not yet well understood. While on this study, unwanted side effects, health problems, complications, or injury, both expected and unexpected, are possible. There may be risks or side effects with the AB-101 treatment regimen which are currently unknown. These effects may be serious, permanent, or even life-threatening. Your condition could worsen while receiving this study treatment. You should discuss these risks with your study doctor.

The AB-101 treatment regimen may cause side effects that may require medical intervention to protect your safety. For your safety, you must discuss any changes in your health and wellbeing

that you experience while you are participating in the study with your study doctor, along with any changes to medications that you are taking, including new medications.

RISKS ASSOCIATED WITH AB-101

This study is the first one to use AB-101 in combination with rituximab or obinutuzumab to treat subjects with lupus. The combination of AB-101 with rituximab, however, has been observed to be safe and well tolerated in an ongoing study for treating Non-Hodgkin Lymphoma, a type of cancer of the lymphatic system. The combination of AB-101 with obinutuzumab has not been studied in clinical trials. The use of AB-101 in combination with rituximab or obinutuzumab to deplete your B-lymphocyte cells may result in decreasing your body's immune response and make you more susceptible to infections. The Sponsor does not yet know of all the possible side effects when subjects are treated with AB-101. Therefore, while receiving AB-101, your safety will be monitored closely with regular physical examinations and blood tests.

AB-101 is a cell therapy, and other cell therapies have been known to cause cytokine release syndrome (CRS), and neurotoxicity.

- **CRS** occurs when your immune cells release small proteins called cytokines. The increase in these cytokines can result in mild flu-like symptoms such as fever, chills, fatigue, and weakness. Sometimes, serious or fatal reactions may occur, and these include symptoms of low blood pressure, increased heart rate, difficulty breathing and organ failure.
- **Neurotoxicity** may cause temporary or serious neurological (or brain related) side effects like confusion, slurred speech, and seizures.
- GvHD or graft-versus-host disease may occur when the administered immune cells attack normal tissues of the recipient or the host. This may cause minor symptoms like a skin rash to more serious cases involving major organs like the liver or gastrointestinal tract.

If you experience any symptoms after receiving a dose of AB-101, contact your study doctor as soon as possible to report these events. We do not yet know all of the possible side effects of AB-101, and we also do not know how well the AB-101 treatment regimen combines with alcohol or with other drugs, and so you should always discuss your use of alcohol or any other drugs (including over-the-counter, prescription, illegal, or herbal) with your study doctor while you are participating in this study.

RISKS ASSOCIATED WITH CYCLOPHOSPHAMIDE AND FLUDARABINE:

Cyclophosphamide and fludarabine, when given alone or together, are intended to lower your white blood cell count. When this happens, you may be at increased risk of infection, bleeding and/or anemia, and/or feeling tired or weak.

Other side effects sometimes seen with these drugs include

- Fever
- Chills
- Nausea
- Vomiting

- Diarrhea
- Loss of appetite
- Infertility (specifically, these chemotherapy drugs are known to cause damage to ovaries in women and testes in men, and to impair egg and sperm formation)
- Hair loss

Rare side effects that could possibly become life-threatening or fatal may include

- Urinary tract damage (with or without blood in urine)
- Heart or lung damage
- Secondary cancers
- Blockage of the veins in the liver
- Decreased sodium in blood.

These listed side effects are for full doses of cyclophosphamide and fludarabine, but the doses given in this study are much lower and therefore less likely to cause these side effects.

RISKS ASSOCIATED WITH RITUXIMAB OR OBINUTUZUMAB:

There are some known risks for rituximab or obinutuzumab that your study doctor will discuss with you and will be monitoring you closely for during the study. These include:

- Flu-like symptoms
- Headache
- Fever
- Chills
- Infections
- Stomach pain
- Nausea
- Diarrhea
- Heartburn
- Flushing (redness)
- Night sweats
- Weakness
- Muscle or joint pain
- Back pain
- Dizziness

Rarely, subjects have experienced severe allergic reactions including hives, difficulty breathing, swelling of the throat or face and severe skin reactions. Contact your study doctor immediately if you experience any of these severe reactions.

RISKS ASSOCIATED WITH CHEST CT SCANS:

CT scans create images of your body using special x-ray equipment, and this will be used to scan your chest area to assess the health of your lungs. During a CT scan, you are exposed to a limited amount of radiation. The amount of radiation during a CT scan is more than what you would be

exposed to during a regular x-ray. With radiation exposure, there may be a very small potential increase to your risk of developing cancer.

During the CT scan, an IV contrast dye (a liquid used to improve pictures of the inside of the body) may be used. The IV contrast dye will enter your body through a needle that is inserted into a vein of your arm. IV contrast can cause allergic reactions that may be mild (for example, rash or itchiness) or, rarely, can be life-threatening. Please notify the study doctor if you have ever had an allergic reaction to contrast material.

The radiation exposure during a CT scan may harm an unborn baby, so please notify the study doctor if you think you may be pregnant or are considering becoming pregnant in the next 6 months.

During the insertion of the needle (used to inject the CT scan IV contrast dye, if this is used), you may feel discomfort. Occasionally, it can cause light-headedness or fainting. You may also experience bruising or swelling at the injection site. There are also very small risks of infection, excess bleeding, or impaired clotting at the injection site.

RISKS ASSOCIATED WITH HAND MAGNETIC RESONANCE IMAGING (MRI) SCANS:

If you have systemic lupus erythematosus with joint involvement, an MRI scan of both hands may be done before study treatment begins, and then repeated at six months and one year later. These scans use strong magnets to generate the pictures so precautions will be taken to ensure that nothing metallic is on or in your body during scanning. These scans are painless and safe, but a contrast media may be injected to enhance the quality of the pictures. You may feel a cold sensation when the contract media is injected, or you may be allergic to the media, or risk infection, bleeding and pain at the injection site.

RISKS ASSOCIATED WITH ECHO AND MUGA

An echocardiogram, or ECHO, uses ultrasound waves to obtain information about your heart. It is considered a noninvasive procedure and does not use radiation. Some people may feel uncomfortable having to lie in one position for the test, but you should feel no major discomfort during an ECHO. You may feel a coolness on your skin from the gel on the transducer and a slight pressure of the transducer on your chest.

A MUGA, or multi-gated acquisition scan, is a test used to obtain information about your heart. It works by generating video images of the lower chamber of the heart to determine if blood is pumping properly. During a MUGA, you will have radioactive tracer injected into one of your veins. A camera will watch how the tracer behaves in your heart to see how your heart is functioning. Risks associated with MUGA may include nausea or vomiting, diarrhea, rash, fatigue, pain, bleeding, bruising, or fainting. The scan will expose you to radiation.

RISKS ASSOCIATED WITH 12-LEAD ELECTROCARDIOGRAMS (EKG):

12-lead EKGs are painless, but the sticky pads used to attach the electrodes to your chest may feel cold when they are first applied to your skin. Some people may develop a mild rash or skin irritation where the sticky pads are placed or discomfort when the sticky pads are removed.

RISKS ASSOCIATED WITH PULMONARY FUNCTION TESTING:

Pulmonary function tests are painless, but you may feel dizzy, lightheaded, or tired from breathing in and out so deeply. These symptoms should go away shortly after you complete the test.

RISKS ASSOCIATED WITH BLOOD SAMPLING:

Blood samples will be drawn from an existing intravenous catheter (a plastic tube placed in your vein) where this option is available, but we may have to insert a needle to access a vein to obtain the sample. You may feel some pain or discomfort during blood sampling if we are drawing blood from your arm. Besides discomfort, blood sampling may also cause bruising or swelling at the injection site. There are also very small risks of infection, excess bleeding, or impaired clotting at the injection site. Blood collection may also occasionally cause light-headedness or fainting.

UNEXPECTED RISKS:

Unknown risks and side effects are possible, and you could experience a side effect that could not be predicted or has never been seen before with AB-101. There is a chance that you could have an allergic reaction to AB-101 or to one of the ingredients used to make it. There is also a chance that other medications you may be taking could interact with AB-101. For your safety, you must tell a member of the study team about all medications that you are taking before you start the study. Also, please tell a member of the study team before starting any non-study medications, including any over-the-counter medicines such as cough and cold remedies.

REPRODUCTIVE RISKS:

The treatments used in this trial may be harmful to an unborn baby, and you will be given a pregnancy test before you are enrolled into the study and at various times throughout the study. Women who are already pregnant or nursing a child are not permitted to take part in this study. Avoiding sexual activity is the only certain way to prevent pregnancy, but if you choose to be sexually active you must use medically *acceptable* birth control.

If you are a woman of childbearing potential (able to have children), you must agree to avoid becoming pregnant during the study. You must also use one of the following methods of birth control from before you enter the study until six months after the last study drug administration :

- Two of the following effective contraceptive methods used together:
    - Oral inserted, injected, or implanted hormonal methods of birth control
    - Copper containing intrauterine device (IUD)
    - Male or female condom used with spermicide
    - Male partner with vasectomy (confirmed absence of sperm in ejaculate)

  - Bilateral tubal ligation or bilateral salpingectomy (tying off or surgical removal of the Fallopian tubes)
- Abstinence or not being sexually active

You should not donate eggs during the study or for 6 months after the last dose of study drug.

If you are a man with a female partner of childbearing potential (able to have children), you must take precautions to avoid impregnating your partner. You must also use one of the following methods of birth control from before screening until six months after the last study drug administration:

- Barrier methods (for example, male or female condom with spermicide)
- Abstinence or not being sexually active
- Vasectomy (confirmed absence of sperm in ejaculate)

You should not donate sperm during the study or for 6 months after the last dose of study drug.

Please notify the study doctor if you or your partner becomes pregnant. In the event that you become pregnant during the study, the Sponsor will be informed about pregnancy and outcome, delivery, and health of the newborn. If you are a male subject in this study and your female partner becomes pregnant, she may be asked to provide informed consent so that information about the pregnancy can be collected.

NEW INFORMATION

You will be told about any new information that becomes available while you are in the study. You may be asked to sign a new consent form if this new information affects your safety, or the procedures used in the study.

BENEFITS

AB-101 was designed to destroy defective B-lymphocyte cells in your body but it is not known if you will personally experience any improvement in your lupus nephritis or systemic lupus erythematosus, or any other benefits from participating in this study. Information collected from your participation in this study may benefit other patients in the future.

COSTS

The AB-101, rituximab, cyclophosphamide, fludarabine and services performed for research only will be provided at no charge to you or your insurance company. Routine medical care performed while participating in study will be billed to you and/or your insurance company. This will include (but is not limited to) physical exams, administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments

and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the Sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION

You will not be paid for your participation in this study. You may, however, be reimbursed up to $48.00/study visit for your out-of-pocket costs related to travel to the clinic for study visits, such as taxi fees. Transportation related reimbursement requires prior Sponsor approval and will be assessed on a case-by-case basis. You will be paid following each completed visit.

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and [for amounts >$50] Social Security number for financial compliance purposes.

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the study sponsor or its research partners. There are no plans to provide financial compensation to you should this occur.

ALTERNATIVE TREATMENT

You do not have to take part in this study to receive treatment for your lupus nephritis or systemic lupus erythematosus. There may be other available treatments for your lupus nephritis or systemic lupus erythematosus. You can also choose to receive no further therapy for your lupus nephritis or systemic lupus erythematosus. Please talk to your doctor to discuss these and other alternative treatments. You will be informed promptly if any significant new information becomes available about AB-101 that may affect your decision to stay in the study.

COMPENSATION FOR INJURY

You will be given medical treatment if you are injured from taking part in this study.

If you think you have been injured by taking part in this research study, tell the study doctor or the person in charge of it as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

If you experience illnesses or injuries related to your participation in the study, medical treatment will be provided to you. The medical costs of diagnosis and treatment may be covered by the Sponsor as long as the AB-101, rituximab, cyclophosphamide, and fludarabine was given correctly and according to the Sponsor's instructions, and the injury was not due to the natural

progression of a pre-existing condition. Please speak with the study team if you have questions about coverage of costs for injury.

If you are insured by Medicare, any costs related to injury paid for by the Sponsor must be reported to Medicare. This reporting may require the Sponsor to have certain identifying information about you so that they can let Medicare know that they made the payment.

The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

Will my study-related information be shared, disclosed, and kept confidential?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve some loss of privacy and the potential for a breach of confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Research records provided to authorized, non-site personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

If you decide to participate in this study, some private health information about you will be stored in a computer database at the site. This information will be placed within your research record and will include your name, medical record number, and other health-related information collected by your doctor. This identifiable information will be kept with the research data at the site, and stored as follows:

- Some hardcopy research data and records will be maintained in a secure location at the site. Only authorized individuals will have access to it.
- Most research data and records will be stored electronically on a secure network with password protection.
- The study doctor is required to keep the research data and records for 2 years after the last marketing approval, or after research on the product is discontinued.

In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information.

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for

regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

- *Office for Human Research Protections or other federal, state, or international regulatory agencies*
- Food and Drug Administration
- *Banner University Medical Group and Banner Health*
- *Advarra IRB*
- *The University of Arizona (UA) and the UA Institutional Review Board*
- *The sponsor supporting the study, their agents or study monitors*
- Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?
Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Patient/subject name
- Address street location
- Address town or city
- Address state
- Address zip code
- Elements of dates (except year) related to an individual (i.e., DOB, admission/discharge dates, date of death)
- Telephone number
- Electronic mail (email) address

- Social security number
- Medical record numbers
- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.
Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?
There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?
You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

What do I need to know if I decide to cancel my authorization?
After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note

that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. The Principal Investigators address and telephone numbers is listed on the first page of this form.

Will access be limited to your research study record during this study?
You may not have access to the research information developed as part of this study until it is completed.

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 this form.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

A US federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or if you are a member of the military.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the Sponsor without your consent for any reason, including:

- If it is in your best interest.
- You do not follow the directions and requirements of the study.
- The Sponsor, US FDA, or Institutional Review Board (a group of people who review the research with the goal of protecting the people who take part in the study) stops the study for any reason.
- You do not consent to continue in the study after being told of changes in the research that may affect you.

If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

SUBJECT RESPONSIBILITIES

If you decide to take part in the study, you will be expected to:

- Keep all appointments scheduled by the study staff. You will also have to agree to follow all instructions given by the study doctor and study staff.
- Report to the study doctors any changes in your physical or mental condition, whether you think these changes may be due to study drug. This is important for your safety and the value of the study.
- Discuss ALL your current medications and supplements (for example, vitamins and other over-the-counter products) with your study doctor and study staff at each clinic visit. You must also let them know of any changes made to your medications in between visits.
- Agree not to participate in other research studies while on this clinical trial. Please inform your study doctor immediately if you are participating in another research study.

SOURCE OF FUNDING FOR THE STUDY

The Sponsor, Artiva Biotherapeutics, will pay for this research study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

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, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00073659.

The IRB cannot answer study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at BannerResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the study doctor listed on page one of this document.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial is 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, this web site will include a summary of the results. You can search this Web site at any time.

STATEMENT OF INFORMED CONSENT

I have read this informed consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date

YOU WILL BE GIVEN A COPY OF THIS FORM TO KEEP