Subject Information and Consent Form
For Part A

Study Title:	A 2-Part Phase 2 Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of BIIB059 in Subjects with Systemic Lupus Erythematosus and Active Skin Manifestations and in Subjects with Active Cutaneous Lupus Erythematosus with or without Systemic Manifestations
Study #:	230LE201
Sponsor:	Biogen MA Inc.
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Purpose of the Subject Information and Consent Form

This Subject Information and Consent Form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your study doctor will be paid by the sponsor (Biogen MA Inc.) to conduct this research study.

Introduction

You are invited to take part in a clinical research study. To help you decide, you should understand the information in this form and what it will involve for you. To make an informed decision to take part – you should know the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

It cannot be promised that the study will help you but in the future the information we get from this study may help improve the future treatment of people with Systemic Lupus Erythematosus.

Once you have decided that you want to take part, you will be asked to sign the informed consent form. You will be given a copy of the signed form to keep, and the original will stay at the study center.

The drug in this study (called BIIB059) is an experimental drug. “Experimental” means that the study drug is currently being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

The study will take place over approximately 40 weeks and will include about 13 office visits to the study doctor.

This is a 2-part study. Part A of the study, which you are being invited to take part in, is for people who have Systemic Lupus Erythematosus (SLE) with an active joint and skin disease. This study will look at how well different doses of the experimental drug works in reducing active joint and skin disease and other lupus manifestations in participants with SLE during a 24 week dosing period. This study will also look at how well participants tolerate the doses of BIIB059 being tested in this study and what happens to the drug in the body; for example, how long it remains in your blood and how quickly it is removed from your body.

BIIB059 is an immunoglobulin of the class G type. An immunoglobulin is a kind of antibody found naturally in your body; class G antibodies are the most common type of antibody found in the body. BIIB059 has been made to bind to a specific cell in the body that is involved in causing SLE. The drug is supposed to act by affecting this cell to help prevent and/or decrease the symptoms of SLE.

This study will take place at about 130 study centers in the United States, Europe, Latin America and Asia. A total of about 190 people will take part in Part A of this study.

This study is a randomized, double blind, parallel-group, placebo controlled study. This means that you may be assigned to receive BIIB059 or you may be assigned to receive an inactive substance. A placebo is an inactive substance that looks just like the BIIB059 but contains no drug.

Randomized means you will be assigned by chance, like the flip of a coin, to one of two dosing groups. Neither you nor the study doctor or study staff will be able to pick which group you are in. Double blind means that neither you nor the study doctor/study staff will know which group you have been assigned to, but the study doctor will be able to find this out quickly if he/she needs to during the study. This kind of study design helps to remove any bias that may be introduced from knowing what dose you received.

Be aware that this form refers to BIIB059 and placebo as “study drug.”

Expenses and payment

There will be no cost to you for taking part in this study. You will be provided with all study drugs, examinations and care related to the study at no cost to you.

You will get a total of up to $702 if you finish the whole study. If you do not finish the whole study, you will get $54 for each study visit you finish. The study doctor or study staff can tell you more about when you will get paid.

What will you have to do?

- You will have to go to the study visits, follow the instructions the study doctor gives you and take the study drug as directed.
- You must not take part in any other studies while you are taking part in this study.
- If you cannot follow the instructions of study staff, you may be withdrawn from the study.
- The study doctor may also decide that it is not in your best interest to take part in the study or continue in the study after the study begins.
- Upon study completion or early withdrawal, it is important for you to speak with your study doctor to consider follow-up care.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

If you are currently taking certain medications to treat your SLE (such as corticosteroids), you may need to be tapered off of these medications once you begin the study. Tapering means that you will reduce the amount of the medication taken over time, in a controlled way (as directed by the study doctor), until you can safely control your disease on a reduced and stable dose of the medication. Throughout the study, you will need to keep a diary of certain medications you are taking. This diary will be reviewed by study staff at every visit.

If you decide to be in this study, you might also have to stop taking your regular medication during the entire study.

If you qualify to enter the study, you will be assigned to one of two dosing groups (on Day 1 of the Dosing Phase):

- 450 mg BIIB059, given subcutaneously every 4 weeks
- Placebo given subcutaneously every 4 weeks

You have an equal chance of being in any of the groups. This means that you have an equal chance (1 in 2) of receiving study drug or placebo. You will receive 450mg study drug or placebo every 4 weeks, with an additional “loading dose” at Week 2 for a total of 7 doses (Weeks 0, 2, 4, 8, 12, 16, and 20). You will receive the same dose (450 mg or placebo) each time. Study drug will be given by subcutaneous injection, meaning an injection into or under the skin.

If you were previously enrolled into the study and you have already started dosing, your dosing will not change. You will stay in your current dosing group.

There are three periods in this study. The first part is the Screening Period. During the Screening Period, the study doctor and study staff will perform evaluations to determine if you are eligible to take part in the study. The Screening Period will last up to 4 weeks. If you are eligible to take part, you will then enter the Dosing Period. The Dosing Period will last 24 weeks. Follow-up visits will be conducted 4, 8, and 12 weeks after the last dosing period visit (Week 24 or end of dosing).. The Follow up Period will last 12 weeks.

During the Screening Period, the following procedures will be done to determine if you are eligible to take part in the study:

- Collection of your gender and year of birth.
- Medical history, including your history of SLE and all medications you are taking.
- Physical exam including weight and vital signs (blood pressure, heart rate and oral body temperature).
- Electrocardiogram to look at the electrical activity of your heart (repeated only once during the Dosing Period, at Week 24).
- Blood tests to determine if you have tuberculosis (an infection of the lungs), hepatitis B and C (disease of the liver) or HIV (the virus that attacks the human immune system and causes AIDS). The study doctor or study staff will tell you if the test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department.
- Urine test for drugs of abuse. The study doctor or study staff will tell you if the drug test results are positive. The results of the drug test must be negative in order for you to be in the study.
- Blood test to determine if you are pregnant (if you are a female able to get pregnant). The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.
- Several assessments of your SLE will be completed by the study doctor and/or study staff.
- Routine blood tests to look at your blood chemistry and cells in your blood; other blood tests to look at how well your blood clots and the antibodies present in your blood.
- Routine analysis of your urine.
- Joint count is an assessment that will be done on your joints it will be carried out on 28 joints.

If you qualify to continue in the study, you will return to the study site for Day 1 of the Dosing Period. You will be assigned to one of two groups on Day 1 and the following tests will be completed; once these are completed, you will receive your first dose of study drug:

- Urine pregnancy test if you are a female who is able to become pregnant (this will be repeated at every visit except the Week 1 visit).
- Physical exam (repeated at every visit except the Week 1 visit and the Week 8 follow-up visit). Your height will only be measured once at the Day 1 at baseline Visit.
- Vital signs (repeated at every visit).
- Blood sample to look at the level of study drug in your blood (repeated at every visit). At Day 1 and Week 4 visits, samples will be taken 4 hours after your study drug dose.
- Routine safety tests of your blood's ability to clot, your blood cells, blood chemistry and urine.
- Testing of your blood for antibodies to the study drug and other antibodies.
- Blood samples to look at levels of immunoglobulins (antibodies that are part of your normal immune system; they fight off infections in your body).
- Blood samples to test how much of your previous vaccine protection remains—that is, the level of protective antibodies remaining from earlier vaccinations (this will be repeated at the Week 24 visit).

- Photographs of the area of active skin disease (repeated at Day 1, Weeks 4 and 16 only).
- Skin tape harvesting, which uses tape to collect samples of active skin (at Day 1, Weeks 4 and 16 only).
- Assessments will be completed by the study doctor and his/her staff at this visit and throughout the study; for example, the CLASI-A and CLASI D score your disease activity (such as how much redness and skin damage there is in an affected area); the SLEDAI-2K and BILAG-2004 also scores your systemic lupus activity (this is completed only if you have systemic lupus at baseline). These assessments will be repeated at most study visits.
- Quality of Life questionnaires (SF-36 and Lupus QoL) will be completed by you throughout the study. These questionnaires ask about your general well-being and limitations in your physical, social and/or daily activities due to your disease.
- You will also complete questionnaires called Global Impression of Change of CLE and a Global Assessment of Fatigue, Pain, Itch, Skin Health and Overall Health. These questionnaires will ask you how you feel with your skin condition.
- Evaluating whether you have had any side effects to the study drug and/or any changes in medications will occur at every visit.
- Other lab tests will also be done to look specifically at the effects of the study drug on the body and your body chemistry; these tests are done on a sample of your blood. The study will also look at markers in your blood and skin, in order to try to predict the response you will have to the study drug. All of these tests are done at almost every visit during the study.
- The study doctor will complete the Global Assessment of CLE and the Global Assessment of SLE at this visit and then again throughout the study.
- The study doctor will also complete the Physicians Global Impression of Change of CLE at Weeks 4, 12, 16 and 24.
- An electronic diary review of subject-reported questionnaires will be done.
- Review of corticosteroid diary will be done at all visits.
- Joint count assessments will be done throughout the study.

Study Visits and many of these assessments will be repeated at Week 1 (Day 8), Weeks 2, 4, 8, 12, 16, 20 and 24, although as shown above, not every assessment is completed at every visit. Your first study drug doses will be given at Day 1 and then again at Weeks 2, 4, 8, 12, 16 and with the last dose given at Week 20.

Once you enter the Follow-up Period, you will be seen at Weeks 4, 8 and 12. The final study visit is the Week 12 follow-up visit. The total duration of the study (after the screening period) is about 36 weeks.

This study will also look at the safety and efficacy of the study drug by race and ethnicity. This is to determine if these factors make a difference in how well the study drug works or if the study drug affects certain groups of people differently than others. For that reason, your race and ethnic background will be collected during this study and entered into the same database where other data about you (such as the disease being studied) will be entered and stored. Your race

and ethnic background are considered data that can potentially identify who you are. Please see the section on data confidentiality below titled “Will your taking part in this study be kept confidential and how will your personal information be used?”

What will happen to any samples you give?

All specimens and samples obtained from you during this study will be used and kept for the purposes described in this Informed Consent Form. All data and materials created during this study will be the property of Biogen. Biogen has no plans to pay you or to share with you any potential profits that Biogen may receive from your specimens, samples, data or materials. Your samples can be used by those working on behalf of Biogen and affiliates of Biogen and may be shared with Biogen’s research collaborators for research purposes.

You should ask the study doctor or study staff about how long your samples might be kept.

Your samples will not be labeled with your name or other directly identifying information. Your samples will have a code instead. The list that matches the code with your name will be stored separately from your samples.

If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor’s policies. You can ask the study doctor or study staff about this.

About photography

The study doctor of study staff will photograph areas of skin disease for the Screening Period and to examine the effects of study drug on your SLE. This could include areas on the face.

You do not have to let the study doctor or study staff take photos if you don’t want to. However, you cannot be in the study if you do not want the study doctor or study staff to take photos.

Before the photographs are given to the sponsor, a black bar will be digitally added to the photographs to cover your eyes or mouth in the picture. If there are identifying marks in other photos (such as tattoos) these will be masked.

What alternatives are available?

Taking part in this study is voluntary – you do not have to take part to receive help for your condition. Your study doctor will discuss with you any treatments or investigational drugs that may be available, and will also discuss their risks and benefits. If you decide not to take part in this study it will not affect your ability to receive medical care.

In addition, you may discuss your options with your regular health care provider.

Belimumab is the only drug specifically approved to treat SLE. Prednisolone and methylprednisolone are two steroids commonly used to treat SLE; the anti-malarial treatment chloroquine is also used to treat SLE. Drugs that suppress the immune system are also used to treat flare-ups that are moderate to severe SLE; these include cyclosporine, azathioprine, mycophenolate mofetil, cyclophosphamide, hydroxychloroquine, methotrexate and prednisone.

What could be the side effects of the study drug?

STUDY DRUG RISKS

There are risks to being in any research study. One risk is that you may get a study drug or dose of a study drug that does not help your disease, or the study drug may make your disease worse. Another risk is that there may be side effects.

There may be side effects that are currently unknown or that are unpredictable. All the side effects of BIIB059 are not known. The effects of BIIB059 when combined with other drugs or substances such as alcohol are not known. A combination of medicines and alcohol or other substances might result in serious or even life-threatening reactions. Therefore, you should always discuss the use of any medicine (over-the-counter, prescription, herbal, and recreational drug) or substances such as alcohol, with your study doctor before taking BIIB059 and while you are in this study.

Side effects can go away shortly after you stop taking the study drug, but some side effects could be long-lasting, permanent, serious, life-threatening, or even cause death. Everyone in the study will be watched for any side effects, and the study drug may be stopped if it is intolerable or if concerning side effects develop. You should talk to your study doctor about any side effects you have while in the study.

Should information become available that could change your decision to be in this study, you will be told immediately. You can always decide whether or not to continue being in this study. As new risks are identified, you will also be told of these risks. At times you may be asked to sign a new consent form that shows that you have been made aware of the new risks and agree to continue taking part in this study.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

BACKGROUND INFORMATION (EXPOSURE)

In clinical study (Study 230LE101), 63 healthy volunteers, 16 participants with systemic lupus erythematosus received BIIB059 and 24 healthy volunteers, 8 participants with systemic lupus erythematosus received placebo, in single doses (injected into a vein) or in multiple dose (injected under the skin).

In the completed Study 230LE101, dosing with BIIB059 in healthy volunteers and participants with systemic lupus erythematosus was well tolerated.

POSSIBLE SIDE EFFECTS

As with all drugs, BIIB059 can cause side effects, although not everybody gets them. Like all drugs, it is possible that BIIB059 can cause side effects that are not yet known.

When animals were administered BIIB059 every 2 weeks for up to 26 weeks, no side effects were observed.

Side effects that have been seen in people dosed with BIIB059 in the completed clinical study 230LE101 are described below. It is not known if these side effects were caused by BIIB059.

In healthy volunteers who received 1 dose of BIIB059 in Study 230LE101, some people have experienced the following side effects:

- upper respiratory tract infection
- headache
- nausea
- laceration (cut)
- or streptococcal pharyngitis (strep throat)

In participants with systemic lupus erythematosus who took 1 dose of BIIB059 in Study 230LE101, some people experienced the following side effects: diarrhea, gastritis (upset stomach), non-cardiac chest pain (chest pain, not a heart attack), and upper respiratory tract infection. One participant who received BIIB059 experienced the side effect of shingles (Herpes zoster), that was assessed as related to the study drug by the Investigator.

In healthy volunteers who received multiple doses of BIIB059 in Study 230LE101, some people experienced the following side effects: headache, hypertension (high blood pressure), nausea, and upper respiratory tract infection.

In participants with systemic lupus erythematosus who took multiple doses of BIIB059 in Study 230LE101, some people experienced the following side effects: back pain, and urinary tract infection.

POSSIBLE SERIOUS SIDE EFFECTS

Serious side effects are those side effects that may lead to hospitalization, could be life-threatening, may be medically important, or may cause death. During Study 230LE101, 3 participants with systemic lupus erythematosus experienced serious side effects. The serious side effects experienced by the first participant, starting 77 days after the last dose of BIIB059, were the following: non-cardiac chest pain (pain in the chest, not a heart attack), gastritis (stomach infection), anemia (low iron in blood), leukopenia (low infection fighting cells in blood), respiratory distress (trouble breathing), subarachnoid hemorrhage (bleeding around the brain), fungemia (fungus in the blood), cerebral vasoconstriction (temporary decrease in blood flow inside the brain), and Clostridium difficile colitis (inflammation of the large intestine caused by an infection). The second participant experienced the serious side effect of osteonecrosis (death of hip bone tissue) 5 days after the first injection. The third participant experienced the serious side effect of colitis (large intestine inflammation from an infection) 95 days after the last dose. All of the serious side effects were considered not related to the study drug by the clinical investigators.

OTHER POSSIBLE SIDE EFFECTS

Exposure to Sunlight: The effect of BIIB059 on the skin, especially when in direct sunlight or with artificial ultraviolet light (e.g., tanning booths), is not known. Thus, you should wear clothes that cover your body (e.g., long sleeves, pants) and use a broad spectrum sunscreen with a

"sun protection factor" (SPF) of 15 or more when you are in the study and for at least 30 days after the last dose of BIIB059. Try to stay out of the sun during this time.

Vaccinations: Tell your study doctor if you have had a recent (for example, in the last couple of months) vaccination (a shot) or are scheduled to get vaccinated. You should not receive certain vaccines after starting BIIB059. Vaccinations that you get while taking BIIB059 may not work or could result in an increased risk of infection. Tell your study doctor if anyone in your household is scheduled to receive a vaccination.

It is possible that receiving BIIB059 may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- a fast pulse
- sweating
- a feeling of dread
- swelling around the eyes and mouth
- swelling of the throat
- wheezing
- having a hard time breathing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- inability to breathe without assistance

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

If I stop or change the dose of my regular medication, what are the risks?

If you stop or change the dose of your regular medication to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication.

What if I am receiving placebo instead of active drug during the study?

Some people in the study will get placebo instead of BIIB059. Placebo is a substance that looks like BIIB059 but has no drug in it. If you receive placebo during the study, it is possible that your

SLE may get worse. Please ask the study doctor or study staff if you have any questions about placebo.

RISKS DURING PREGNANCY AND BREASTFEEDING

We do not know whether BIIB059 affects human fertility or the unborn baby. Studies in animals that test whether BIIB059 has an effect on an unborn baby, on sperm, or on the development of babies during pregnancy have not been done to date.

Women

We do not know the effects of BIIB059 on unborn babies. Some drugs cause premature (early) birth or birth defects. Therefore, it is important that you do not become pregnant during the study or for 4 months after your last dose of study drug. You can enter this study only if you are past menopause (i.e., you no longer get your period), are surgically sterile (i.e., you have had a hysterectomy), have been surgically sterilized (e.g., bilateral tubal ligation), or are using highly effective birth control methods.

For the purposes of the study, highly effective contraception for women is defined as use of 1 of the following:

- Established use of oral (birth control pills), injected, or implanted hormonal methods of contraception.
- Placement of an intrauterine device or intrauterine system.
- Vasectomy of male sexual partner (with the appropriate post-vasectomy documentation of the absence of sperm in the ejaculate).

Your study doctor will discuss birth control with you. During the study, we will do pregnancy tests on women who can become pregnant. You must stop taking study drug and tell your study doctor immediately if you think that you are pregnant. Your study doctor will ask you for information on the outcome of your pregnancy and may send this information to the sponsor.

If you are breastfeeding, you cannot take part in this study because it is not known whether BIIB059 goes into breast milk and affects your baby.

You must not donate eggs while taking study drug or for 4 months after stopping study drug dosing.

Men

You and/or your partner must use highly effective birth control during your dosing and during the 4 months after dosing. For men, effective contraception includes a vasectomy with negative semen analysis at follow up, or the use of condoms with spermicide.

If your partner becomes pregnant during the study or for up to 4 months after your last dose of study drug, notify the study doctor.

You must not donate sperm while taking study drug or for 4 months after stopping study drug dosing.

If your partner becomes pregnant you should report it to the study doctor. The study doctor will request information about the outcome of the pregnancy

Women and Men

Complete abstinence, when this is consistent with your preferred and usual lifestyle, can be considered an acceptable method of contraception based on the evaluation of the study doctor. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not considered acceptable methods of contraception.

CANCER RISK

No animal studies were done to see whether BIIB059 increases the risk of cancer. At present, we do not know if BIIB059 increases the risk of cancer in people.

UNKNOWN RISKS

As with any new drug, there is a risk of rare or previously unknown side effects (which include your health getting worse, or even death) and/or a chance that BIIB059 might interact with other drugs.

OTHER IMPORTANT SAFETY INFORMATION

There are no known contraindications (conditions that prohibit use) to the use of BIIB059, other than an allergy to monoclonal antibodies.

During the study, check with your study doctor before you take any medicines, including medicines that you can get without a prescription, herbal products, or supplements.

Other safety information that you need to know before you start the study:

- Your body might form antibodies against BIIB059. Antibodies are proteins made in your body that fight against unknown substances. They are there to protect your body, but they might prevent BIIB059 from working or might cause an allergic reaction.

You must tell your study doctor if you get any side effect, whether it is listed here or not. If you are worried, contact your study doctor immediately.

If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately (see 'Who should you contact for questions?').

What are the possible disadvantages or risks of taking part?

It is possible that the symptoms of your condition will not improve during the study or may even worsen. Dosing with this study drug may also involve risks to your future health that we currently don't know about. Risks from specific study procedures are described below.

Taking Blood: The risks of taking blood through a needle placed in a vein in your arm include: temporary pain or discomfort from the needle, bruising, clotting, swelling at the needle site, and, in rare instances, infection. You may also experience dizziness, nausea or fainting while blood is being taken. Please tell the study doctor or study staff if you do not feel well after having your blood taken.

The amount of blood that will be drawn at any one study visit is a maximum of about 46 mL (equal to about 3.1 tablespoons). The total amount of blood that will be drawn during the study is about 330 mL (equal to about 1.4 cups).

Electrocardiogram (also called an EKG or ECG): This is a test that looks at the electrical activity of your heart. With each beat of your heart, an electrical impulse (or "wave") travels through the heart. By measuring the time intervals on the ECG, a study doctor can determine if your heart's electrical activity is normal or slow, fast or irregular. An ECG is a safe and painless procedure. The patches that the study staff will stick to your chest and other areas of your body to monitor your heart may irritate your skin and cause itching and/or redness. The study staff might need to shave your body hair so that they can stick the pads to your skin. The shaving may cause some irritation. If you are allergic to the material in the patches, a local allergic reaction could occur. When the sticky patches are removed, it might sting for a few seconds.

Skin Tape Collection: Skin tape collection is considered a potential alternative to a skin biopsy that is less invasive and doesn't break the skin. This procedure allows the study doctor to remove a sample of only the top layers of your skin in the area of active disease; this includes removal of proteins present in the upper layers of the skin. The tape is the size of a small bandage. The purpose of this procedure is to remove cells from the skin and then remove RNA from those cells. RNA, like DNA, is your genetic material; it is found in all cells in your body and it is involved in the activity of all cells. It may help researchers better understand SLE and the skin disease that sometimes occurs in SLE. The risks of this procedure are mainly discomfort when the tape is removed. This can cause discomfort and pain similar to what you would experience when removing a bandage. There may be redness, itching and pain after the procedure is done. You could have an allergic reaction to the tape, although this is not common. If you have an allergic reaction, you may have redness, itching, swelling and/or raised red bumps at the location of the tape.

Questionnaires: Filling out the questionnaires could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire. You have the right to refuse to answer any questions.

Confidentiality: There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

It is possible that people who see the study photographs will recognize you.

Will Being In This Study Help Me?

The study drug may help your SLE, but there is no guarantee that being in this study will help you. Your SLE might not get better or may even get worse while you are in this study. You may get placebo, which is a substance that looks like a drug but has no drug in it. Information from this study might help researchers to better understand SLE or come up with new tests or medications to help others in the future.

What if new information about the study becomes available?

Sometimes new information about the study is received. You will be told if any relevant new information becomes available that may affect your willingness to carry on taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to carry on, your study doctor will consider arrangements for your care to continue. If you decide to continue in the study you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained and arrangements considered for your care to continue.

What happens when the research study stops?

During the study you will receive the study drug free of charge. The study drug may not be available as a prescription paid for by the health care system immediately after the end of the study. There is no guarantee that you will continue to receive this particular drug when you have finished taking part in the study. The care you receive after the study has ended may involve a different drug, which the hospital, together with your regular doctor, considers to be the most suitable alternative.

If you have a reaction to the study drug, your participation may be stopped at any time by the study doctor or sponsor without your consent.

If the study is stopped, you will be told and your study doctor will consider arrangements for continuation of your care.

Compensation for study related injury

You can obtain medical treatment for an injury resulting from dosing with study drug at the study center. For further details, or if you believe you have been injured as a result of participating in this study, please contact the study doctor at the telephone number on the first page of this form.

If you have any injury resulting from dosing with study drug, Biogen will pay for the reasonable cost of necessary medical care to the extent the cost is not paid by your commercial medical insurance, or another party. You may not be compensated for uninsured medical care if you do

not follow instructions regarding proper use of the study drug. If you have an injury resulting from dosing with the study drug, your study doctor will decide what medical care you need. Biogen will not pay for the normal progress of your disease, or any injury or complication due to the medical condition you already have. Biogen has no plans to provide any other kind of compensation such as compensation for lost wages, disability or discomfort. You do not give up any of your legal rights by signing this consent form.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

What will happen if you don't want to carry on with the study?

You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you stop taking part, please tell your study doctor immediately. You will be asked to return to the study center for an end-of-study assessment. You may also be asked for permission to be contacted at a later date by your study doctor to collect minimum additional data about your condition.

If you withdraw from the study, the study doctor and study staff can still use your information that they have already collected.

Your study doctor may withdraw you from the study if the study is not helping you, if you do not follow the study directions, or if you have a serious side effect to the study drug. The sponsor, FDA, or Quorum Review may also stop the study at any time for any reason. If your study doctor thinks it is in your best interest to withdraw from the study, or if the study is stopped for any other reason, he/she will explain the reasons and consider ways for your care to continue.

Will your taking part in this study be kept confidential and how will your personal information be used?

The information and samples collected from you will not identify you by name, only by a number and your partial date of birth. Your name will not be used in any study reports, and these reports will be used for research purposes only. In addition, the results of this study may be published. In such a case, your personal information will still be confidential, but the results of the study will be more widely distributed.

Biogen and those working on behalf of or providing services for Biogen, affiliates of Biogen, Quorum Review, and various government health agencies (such as the FDA) may inspect, copy and use data and results from the study, including your records. Biogen may use your data and results to see if the study drug works and is safe; to compare the study drug to other drugs; and for other purposes (such as, but not limited to development of new treatments, research, and regulatory submissions). Every effort will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. If you think you were harmed by being in the study, the study team may share your health data with the company health insurer to resolve your claim.

Authorization to use and disclose protected health information for research

Study records that identify you will be kept confidential as required by law. The United States government has issued a privacy rule to protect the privacy rights of participants. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA).The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). The document you are reading, called an "Authorization," explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information.

In working with the sponsor, your study doctor will use and share protected health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results, and certain health information indicating or relating to a particular condition. Photographs are also included. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives (which include companies that are contracted by the sponsor to perform services for the study) may review or copy your protected health information at the study site.

The sponsor and its representatives will use your information to review the study, to check the safety and results of the study and to seek government approval of BIIB059. Regulatory authorities and Quorum Review may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Consent form, you allow the study doctor and study staff to use your protected health information to carry out and evaluate this study. You also allow the study doctor to share your protected health information with:

- The sponsor and its representatives
- The Quorum Review
- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies
- Laboratories for testing biospecimens (as applicable)

Your protected health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Consent form you agree that you might not be able to review or receive your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization to Use and Disclose Protected Health Information for Research at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to the address indicated at the beginning of this document.

If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns a side effect related to the study. If a side effect occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about a side effect related to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new protected health information may be collected until this study ends.

This Authorization expires in 50 years.

You do not have to sign this Authorization, but if you do not, you cannot participate in this research study or receive study drug. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

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.

The results of this study will be used to make informed clinical decisions for developing this new drug. If you want the results to be made available to you, please talk to your study doctor.

Who should you contact for questions?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

Thank you for reading this and considering if you will take part in this study.

Consent and Authorization form

I confirm the following:

- The information about this study has been explained to me.
- I have read the information for the above study, and have had enough time to think about taking part.
- I am satisfied so far that all of my questions have been answered.
- I voluntarily agree to be part of this research study, to follow the study procedures and to provide the information the study doctor or other study staff members ask for.
- I have been told that I am free to choose to stop being part of this study at any time without giving a reason and without my medical care or legal rights being affected.
- I agree to my samples being taken and used as described in this information sheet.

By signing this document I agree to take part in this study, as set out in the information and consent form and authorize the release of my medical records and protected health information related to this study to the sponsor and its representatives Quorum Review, laboratories for testing biospecimens (as applicable), the FDA and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Consent and Authorization for my records.

By signing this form, I do not give up any of my legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date