STUDY PARTICIPANT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A Phase 2, Parallel, Comparator-Controlled Trial to Evaluate the Safety and Efficacy of LY3209590 in Insulin-Naïve Patients with Type 2 Diabetes Mellitus

PROTOCOL NO.: I8H-MC-BDCL(b)
IRB Protocol # 20200169

SPONSOR: Eli Lilly and Company

INVESTIGATOR: Anuj Bhargava, MD
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United States

STUDY RELATED PHONE NUMBER(S): 515-329-6800 (24 hours)

Introduction
You are being asked to voluntarily be in a medical research study of a study drug known as LY3209590.

Eli Lilly and Company and its representatives ("sponsor"), are sponsoring this study and are paying the study doctor and/or the research site for their work in this study.

The purpose of this form is to help you decide if you want to be in this study.

Please read this form carefully. It may contain words that you do not understand. Please ask the study doctor or nurse to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family or friends before making your decision. If you sign this form, you are giving your permission (or consent) to be a part of this study. You can agree to take part in this study and change your mind later.

If any important new information is found during this study that may affect your wanting to continue to be part of this study, you will be told about it right away.

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.

Confidentiality of Trial Information
The information in this informed consent document is intended to help you determine whether participating in this study is right for you. You may wish to discuss this information with others for the purposes of helping you decide whether to participate in the study or as needed for medical treatment. You are asked to treat this information as confidential and to inform any others with whom you share this information that it is confidential. During the course of this study, you and/or a family member or caregiver of yours may learn, or have access to, proprietary information of the Sponsor, including drug product information. Proprietary information should be maintained as confidential. Please ask your study doctor for more specifics if you have a question about the nature of any particular information.

Why is this study being done?
This study is being done to see how safe an investigational drug is and how well it will work to help people with Type 2 diabetes mellitus (T2DM). "Investigational" means that the drug being tested has not been approved for routine clinical use or for the use described in this study by the United States Food and Drug Administration (FDA).

The main reason for you to take part in this study is not to treat you for your condition but to help in answering the following research questions:

- How LY3209590 compares to insulin degludec.
- How safe is LY3209590 and any side effects you might have when you take it.

How many people will take part in the study?
Approximately 375 study participants will be taking part in this study.

What will happen during the study?
You will be asked to:

- sign this consent form;
- give your health history. The study staff will review your medical history and test results to see if you can be part of this study.
- tell the study staff if you take any over-the-counter or prescription drugs, vitamins, or herbs.

The study staff will discuss what is required for you to be part of this study.

To take part in this study, you must have:

- Type 2 diabetes mellitus treated with a stable dose of metformin for at least 3 months.
- An HbA1c value of 7.0% to 9.5%, inclusive.
- A body mass index (BMI) between 20 and 45 kg/m², inclusive.

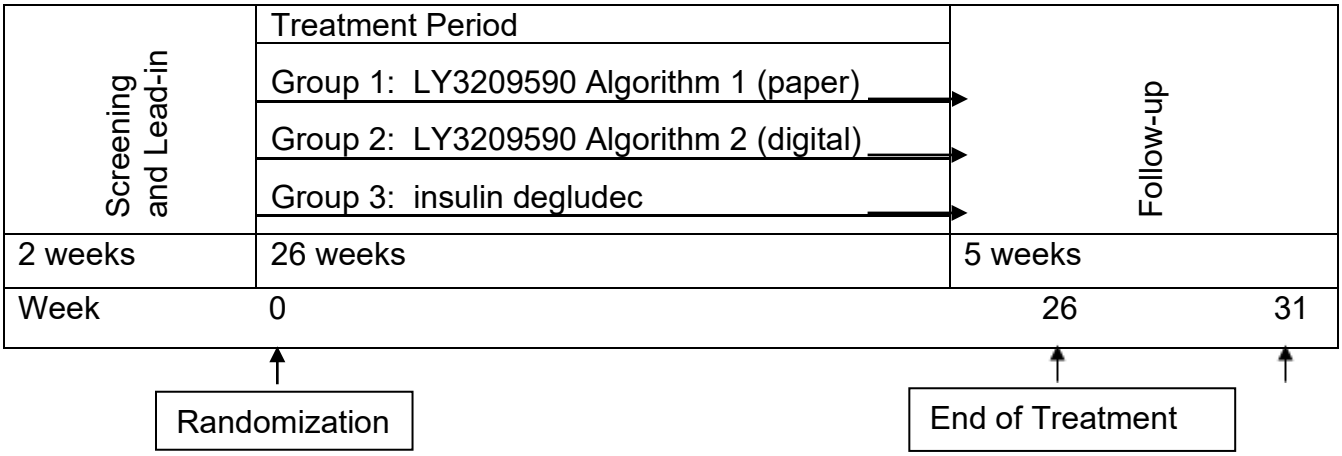
You cannot take part in this study if:

- You have type 1 diabetes mellitus or other type of diabetes.
- You have had any episodes of severe hypoglycemia and/or hypoglycemia unawareness within the past 6 months.
- You have had a heart attack, heart failure, or stroke.
- You have liver disease such as hepatitis or cirrhosis.
- Your kidneys are not functioning well and you have an estimated glomerular filtration rate (eGFR) of less than 30 milliliters/minute/1.73 m².
- You have active or untreated cancer.
- You are on chronic glucocorticoid therapy.

You may need to have some exams or tests done to find out if you are a candidate to begin the investigational drug. Some of these tests may be done even if you do not join the study as part of your normal care.

You will get LY3209590 or insulin degludec to take during this study. If you are in Group 1 or Group 2, you will receive LY3209590 and dose adjustments will be determined at each visit. If you are in Group 3, you will receive insulin degludec. You will know which medicine you are taking. Whether you receive LY3209590 or insulin degludec will be decided by chance (like drawing straws). The chance that you will receive LY3209590 is 2 in 3.

Study Diagram for BDCL



The study will consist of 3 periods: a 2-week screening, a 26-week treatment period, and a 5-week safety follow-up period during which your physician will decide on your further diabetes treatment.

You will be asked to provide self reported data via a tablet device (*for example, if being collected during your office visits*) or a smart phone device (*for example, questionnaires, scales, or diaries* that are completed while at home). In some cases, a medical device (*for example, an actigraphy device that measures heart rate or pulse*) may also be paired to the smart phone device, to collect data. You will be trained by site staff on using the device(s) which/that are designed for ease of use, with limited functionality. If using a smart phone device, the data will normally be set up to transfer automatically, on a regular basis (generally once per day, overnight) to a secure system location. Once you have completed or leave the study, all devices should be returned to your site personnel as soon as possible (unless directed otherwise). Since the smart phone device may be set up to transmit data automatically, any data that you provide in the device, after you have left the study, may also continue to transmit. Therefore, it is highly recommended that you return the device(s) immediately when finished participating in the study. Any data that you provide past your study participation, will be included with the rest of the data provided during participation and included in overall results.

You will:

- use the study drug only as instructed by the study staff;
- return any unused study drug and containers at the end of this study, or as instructed by the study staff;
- be given the study drug by injection under the skin (subcutaneously) by the study staff. Later in the study you will be taught how to self-inject.

It is important that you are completely truthful with the study staff about your health history. It may be harmful to you or to other people who may take the drug if you are not truthful with the study staff. You should not take part in this study if you do not meet all requirements.

If you choose to be in this study, your part in the study is expected to last up to 33 weeks.

Please review the table below. This will give you information about what will happen at each specific visit and how often the procedures will happen.

	Screening Visits		On the Study Drug																	ED		Follow-Up Visit	ET	Comments
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**ED1**	**ED2**	**801**		
Week	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**14**	**16**	**20**	**24**	**26**		**ED1 +5**	**31**		
Fasting visit (no eating or drinking except for water)		**X**	**X**			**X**			**X**						**X**		**X**		**X**	**X**	**X**	**X**	**X**	**X**	At least 8 hours
Procedures:																									
Informed consent	**X**																								
Talk with study staff about your health and any medications you are taking	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	May include medical history or side effects or response to study drug.
Have a physical exam	**X**	**X***	**X***			**X***			**X***						**X***		**X***			**X**	**X**	**X**	**X**	**X**	May include weight, height, and vital signs (heart rate, blood pressure, and body temperature) *Vital signs and weight only.
Approximate blood sample drawn in mL (teaspoons)	**12 (2)**	**30 (6)**	**58 (12)**	**8 (2)**	**3 (1)**	**18 (4)**			**40 (8)**						**45 (9)**		**30 (6)**		**8 (2)**	**50 (10)**	**50 (10)**	**45 (9)**	**45 (9)**	**50 (10)**	Additional samples may need to be collected in the event a re-test is needed.

	Screening Visits		On the Study Drug																	ED		Follow-Up Visit	ET	Comments
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**ED1**	**ED2**	**801**		
Week	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**14**	**16**	**20**	**24**	**26**		**ED1 +5**	**31**		
Fasting visit (no eating or drinking except for water)		**X**	**X**			**X**			**X**						**X**		**X**		**X**	**X**	**X**	**X**	**X**	**X**	At least 8 hours
Procedures:																									
Pregnancy test (WCBP only)	**X***		**X**																			**X**	**X**	**X**	Additional pregnancy testing may be performed if required by local regulations. *Blood test and the rest are urine tests.
Provide a urine sample	**X**																			**X**	**X**	**X**	**X**	**X**	
Have an ECG	**X**		**X***			**X***			**X***						**X***		**X***			**X**	**X**	**X**	**X**	**X**	*Fasting, triplicate ECG.
Participant training and education		**X**																							Includes diabetes counseling, hypoglycemia, BG meter, 6-point SMBG profiles, and diary completion.
Receive BG meter and supplies		**X**	**X**			**X**			**X**						**X**		**X**			**X**	**X**				
Receive electronic diary		**X**																							
Review your diary			**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	

	Screening Visits		On the Study Drug																	ED		Follow-Up Visit	ET	Comments
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**ED1**	**ED2**	**801**		
Week	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**14**	**16**	**20**	**24**	**26**		**ED1 +5**	**31**		
Fasting visit (no eating or drinking except for water)		**X**	**X**			**X**			**X**						**X**		**X**		**X**	**X**	**X**	**X**	**X**	**X**	At least 8 hours
Procedures:																									
Perform 6-point SMBG test prior to next visit		**X**			**X**			**X**			**X**			**X**		**X**		**X**	**X**						
Review 6-point SMBG results			**X**			**X**			**X**			**X**			**X**		**X**		**X**	**X**	X				
Get FGM sensor	**X**												**X**						**X**						Avoid immersion in water greater than 3 feet (1 meter) or for periods longer than 30 minutes.
Return FGM sensor			**X**												**X**					**X**	X			**X**	Do not wear sensor longer than 14 days and if visit interval is greater than14 days, you should remove the sensor and bring to the visit.
Receive training on study drug administration						**X**			**X**			**X**	**X**	**X**	**X**		**X**								
Receive study drug			**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**			**X**							
Return unused study drugs																		**X**		**X**	**X**			**X**	

	Screening Visits		On the Study Drug																	ED		Follow-Up Visit	ET	Comments
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**ED1**	**ED2**	**801**		
Week	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**14**	**16**	**20**	**24**	**26**		**ED1 +5**	**31**		
Fasting visit (no eating or drinking except for water)		**X**	**X**			**X**			**X**						**X**		**X**		**X**	**X**	**X**	**X**	**X**	**X**	At least 8 hours
Procedures:																									
Return electronic diary																				**X**	**X**			X	

Abbreviations: BG = blood glucose; ECG = electrocardiogram; ED = early discontinuation; ET = early termination; FGM = flash glucose monitoring; SMBG = self-monitoring blood glucose; WCBP = women of childbearing potential.

During the study, you should avoid the following:

- Weight loss medicines;
- Weight loss and diet programs;
- Donating blood.

If you are unable to attend a study visit due to COVID-19 or natural disaster-related reasons, you should be willing to accept a home visit where study procedures would be performed by qualified personnel. If a home visit(s) becomes necessary, a second Informed Consent, specific to home visits, would be requested.

Are samples being collected?
Please review the information below. This explains what samples are being collected, how they will be used, and how long they will be stored. Additional samples may be required to repeat a test if needed. The samples and any data generated from the sample can only be linked back to the study participant by the investigator site personnel.

General Information Regarding Sample Collection
Various blood and urine samples will be collected from you during this study. The specific procedures for collecting these samples and the risks associated with collection are explained in the procedure table and risks section in this document. Your samples will be identified by your study participant number, and not by your name.

The analysis of your sample(s) may contribute to the creation of new laboratory tests, new medicines, or other items that may be commercially valuable to the sponsor. The sponsor has no plans to provide you, either now or in the future, any compensation, royalty, or any other financial benefit that might result from any product, procedure, or other item that may be developed from studying your sample(s) or any information or data that is derived from such research.

Samples for Study Qualification and Health Monitoring
Blood and urine samples will be collected to determine if you meet the requirements to participate in this study.

Additional blood and urine samples will be collected throughout the study to monitor your health and your response to study drug.

Blood samples will be tested for hepatitis B, which is a serious and contagious disease. If your test results are positive, your study doctor or staff will contact you.

The results of hepatitis B testing will be kept confidential and disclosed only as required by law. We are required to notify state health authorities of positive results.

All samples collected for Study Qualification and Health Monitoring will be destroyed within 60 days of confirmation of the test results, unless laws, regulations, or international laboratory certification standards require a longer retention period. This confirmation will either occur immediately after initial testing, or may require that samples be held to be retested at a defined later point in time.

Samples for Measuring Study Drug Levels
Blood samples will be collected to measure the amount of study drug that is in your body and how your body breaks it down. The samples will be stored for a maximum of 1 year after this study is finished.

Samples for Genetic Research
Blood will be collected to study your DNA. DNA is genetic material that is found in all the cells of your body. DNA contains instructions that your body reads to understand how it should be built and work. Some of these instructions tell your body how to react to medicines. For this reason, looking at DNA can sometimes help explain why people with a disease respond differently to the same medicine. For example, some people taking this study medicine may respond well. Others may have little or no response, or have side effects.

Researchers may study your DNA to learn how the study medicine works for you. Information about your DNA may be used to create or improve tests to measure these genetic factors. Researchers may also study your DNA to better understand the disease for which this study drug is developed.

The DNA sample may be stored for up to 15 years after this study is finished.

Samples for Biomarker Research
Sometimes scientists measure substances in the body to diagnose, evaluate, or monitor a person's medical condition or disease. For example, cholesterol levels in the blood can be used to monitor a person's risk for heart disease. In this example, cholesterol is a biomarker.

Blood will be collected to identify or better understand biomarkers.

Researchers may use biomarkers to learn more about diabetes mellitus or how study participants respond to study drug or other medicines that you are taking during this study. Your sample(s) may also be used to create or improve tests to help identify study participants in the future who may respond to this study drug.

The sample(s) may be stored for up to 15 years after this study is finished.

Samples for Antibody Research
Blood sample(s) will be collected to determine if your body produces antibodies against the study drug. Antibodies may affect how a drug works in your body if you take it in the future. The sample(s) may be stored for up to 15 years after this study is finished.

You may have blood samples collected up to 1 year after the study ends. The sample(s) may be stored for up to 15 years after this study is finished.

What will happen when I am finished with the study?
The study doctor or one of the doctor's staff members may try to reach you after you have stopped study treatment. They will want to talk to you to see how you are doing. They may also want to ask about any other treatment you received since leaving this study. If you move or lose contact with the study doctor and staff, they may give your name and last known contact information to a third party vendor to try to find your current contact information.

If you are unable to visit the site due to COVID-19 or natural disaster travel restrictions, and home visits are not possible, your transition to another diabetes treatment would exceptionally be guided by telephone visits.

What side effects or risks can I expect from being in the study?
There may be risks to you if you are in this study.

Safety information from 12 healthy volunteers and 350 patients with type 2 diabetes mellitus, who have taken LY3209590 as of 02 October 2019, has been reviewed.

Risks and Discomforts Associated with LY3209590
LY3209590 was made so that it acts like insulin, a hormone made in your body that has many important actions including lowering high blood sugar. People have been taking different types of insulins to treat high blood sugar (diabetes) for many years. However, LY3209590 is chemically different from currently available insulins, and it is made so that it only needs to be injected once a week.

Study participants who have taken LY3209590 reported low blood sugar (hypoglycemia) as the most common adverse event. There was a case of severe low blood sugar that required assistance from another person.

When rats and dogs were given doses of LY3209590 that were higher than doses that will be given to people, rats and dogs had low blood sugar. In particular, long periods of low blood sugar in rats led to bad effects on nerves, muscle, and other organs, including the pancreas (which makes insulin).

Based on animal and human studies, a single injection of LY3209590 to people could lower blood sugar levels, and this could last for 1 week or longer. Hypoglycemia could

cause low energy, hunger, confusion, pounding heart, sweating, shakiness, and headache. Severe hypoglycemia can lead to seizures, loss of consciousness, or coma, and may be life-threatening. Your blood sugar will be checked regularly during the study.

When rats and dogs were given doses of LY3209590 that were higher than doses that will be given to people, rats sometimes had a fatty thickening where LY3209590 was injected.

LY3209590 is a protein that needs to be injected through a needle under the skin, which may cause pain and other reactions at the injection site such as allergic reactions (redness, itching, or swelling). During or shortly after the injection, other allergic reactions may occur elsewhere in the body such as:

- fever,
- chills,
- joint pain,
- muscle pain,
- skin rash,
- urge to vomit,
- dizziness,
- headache,
- throat irritation,
- or shortness of breath.

Less commonly, a more serious reaction may occur such as low blood pressure, wheezing, or difficulty in breathing, and can sometimes be life-threatening. You will be watched for signs of allergic reactions during the study. If you have a serious allergic reaction (seen rarely) to the insulin or any of the ingredients, stop using this medicine and see a doctor straight away. You should get medical help (call 911) and contact the study doctor or staff if you have any of these side effects during the study.

Your body's disease protection system may react to LY3209590 by making antibodies (proteins that look for and get rid of matter in the body that it does not recognize or know). The possible effects of antibodies to LY3209590 in people are not known. Blood samples will be taken during the study to see if antibodies to LY3209590 are formed.

Dogs that were given LY3209590 had increases in heart rate. Your heart rate, blood pressure, and electrocardiograms (a measure of how slow or fast or how regular your heart beats are) will be recorded and checked regularly.

Stillbirths and birth defects have been found in baby animals when pregnant mothers were given doses of LY3209590 that were lower than doses that will be given to people and produced severe low blood sugar in pregnant animals. If you are pregnant,

breastfeeding, or plan to become pregnant during the study, you should not participate in the study. If you are able to give birth to children, you may participate in studies, but should use birth control methods approved by your doctor. If you become pregnant during this study, contact your doctor right away. If you become pregnant during the study you will no longer be given study drug treatment.

Risks for Insulin degludec

You should not use insulin degludec if you are allergic to it, or if you are having an episode of hypoglycemia (low blood sugar) or diabetic ketoacidosis (call your doctor for treatment).

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypoglycemia (low blood sugar) may occur very commonly with insulin treatment (may affect more than 1 in 10 people). It can be very serious. If your blood sugar level falls too much, you may become unconscious. Serious hypoglycemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, take actions to increase your blood sugar level immediately.

If you have a serious allergic reaction (seen rarely) to the insulin or any of the ingredients, stop using this medicine and see a doctor straight away. The signs of a serious allergic reaction are:

- the local reactions spread to other parts of your body (local reactions include pain, redness, hives, swelling, and itching)
- you suddenly feel unwell with sweating
- you start vomiting
- you experience difficulty in breathing
- you experience rapid heartbeat or feeling dizzy.

Call your study doctor right away if you have:

- fluid retention--weight gain, swelling in your hands or feet, feeling short of breath; or
- low potassium--leg cramps, constipation, irregular heartbeats, fluttering in your chest, increased thirst or urination, numbness or tingling, muscle weakness or limp feeling.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Local reactions: Local reactions at the place you inject yourself may occur. The signs may include: pain, redness, hives, swelling, and itching. The

reactions usually disappear after a few days. See your doctor if they do not disappear after a few weeks. Stop using insulin degludec and see a doctor straight away if the reactions become serious. For more information, see 'serious allergic reaction' above.

- Skin changes where you use the injection (lipodystrophy): Fatty tissue under the skin may shrink (lipoatrophy) or get thicker (lipohypertrophy). Changing where you inject each time may reduce the risk of developing these skin changes. If you notice these skin changes, tell your doctor or nurse. If you keep injecting in the same place, these reactions can become more severe and affect the amount of medicine your body gets from the pen.
- Swelling around your joints: When you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This is usually only short-lasting.

Rare (may affect up to 1 in 1,000 people)
This medicine can cause allergic reactions such as hives, swelling of the tongue and lips, diarrhea, nausea, tiredness and itching.

Procedure Risks
Please talk to the study doctor or staff about any questions or concerns that you may have about the procedures required for this study.

Blood Tests
For most people, needle punctures for blood draws do not cause any problems. However, sometimes they may cause bleeding, bruising, discomfort, infections, and/or pain where you had the blood drawn. You may also feel dizzy.

Electrocardiograms (ECGs)
There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.

Flash Glucose Monitoring:
Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain, or skin irritations (for example, redness, swelling, bruising, itching, scarring, or skin discoloration). The chance of this happening is low.

Glucose Monitoring
Blood sugar testing requires pricking your finger and testing a drop of blood. This does not usually cause serious problems, but it can cause some discomfort. In this study, you will be using a glucose meter to monitor your blood glucose levels.

Allergic Reaction of Antibodies to Subcutaneous Insulin
Your body's immune system may react to any insulin, including LY3209590, by making proteins (antibodies) that attack objects that enter the body. These proteins that form

against insulin could cause an allergic reaction. It could also interfere with how your body normally reacts to insulin. This could lead to low or high blood glucose, which would require insulin dose adjustments. Blood samples will be taken to see if your body is forming insulin antibodies. Rarely, some people can have a whole-body allergic reaction which may be life-threatening.

What are the Reproductive Risks?
If you are female, you should not become pregnant or breastfeed a child while in this study. Naturally, the best way to not become pregnant is not to have vaginal sex (intercourse). If you are sexually active, you must use birth control. You should talk with your doctor about the types of birth control that are best for you and your partner. Tell your doctor right away if you become pregnant or think you are pregnant.

Taking part in this study can result in risks to an unborn child or breastfeeding child. Some methods of birth control may be less effective. Methods of birth control for this study include:

Highly effective:

- Combination oral contraceptives
- Implanted contraceptives
- Intrauterine device

Effective:

- Male or female condoms with spermicide
- Diaphragms with spermicide
- Cervical sponges

Either 1 highly effective method of contraception or 2 effective methods of contraception will be used.

Male and female condoms as a double barrier method is not considered acceptable. Barrier methods must include the use of a spermicide.

Please discuss birth control methods with your study doctor.

There may also be unknown risks to your embryo, fetus, or nursing child.

Other Risks
In addition to the side effects already described, LY3209590 and comparator drug(s) and other drug(s) required by the protocol, the combination of the study drugs, and the study procedures may have other unknown risks.

There may be unknown risks of possible harmful interaction with other medication you may be taking.

You should not give the study drug to other people and should keep it out of the reach of small children.

Are there benefits to taking part in the study?
If you receive LY3209590 and it is effective for you, your symptoms may improve while you take part in this study. You may or may not receive any benefit from being in this study. If you take part in this study, your participation will provide information about the study drug. This might benefit other people with Type 2 Diabetes.

Information obtained from this study will also benefit the sponsor of the study and may benefit study participants in the future.

What other choices do I have if I do not take part in this study?
You do not have to take part in this study to be treated for your condition. Other treatments for your condition are available.

Your other choices may include:

- Continuing your current treatment
- Getting treatment or care for your diabetes without being in a study.

Your study doctor will discuss these options, and their risks and benefits, with you.

What happens if I want to stop the study?
Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time. You may do so without a penalty or loss of benefits to which you are otherwise entitled.

Your participation also may be stopped by the study doctor or sponsor for any reason without your consent. If this happens, it might be due to a bad reaction you have to LY3209590 or new information about LY3209590's safety or effectiveness. Other reasons you may be withdrawn are:

- if you need a treatment not allowed in this study,
- if you do not follow the study procedures as instructed,
- if the study is canceled by the FDA or the sponsor.

If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation and how to stop safely. You may be asked to return to the clinic for tests.

What are the costs of taking part in this study?
Study drug and study procedures will be provided at no cost to you. You or your insurance company will have to pay for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

You may have to pay for some expenses related to this study such as childcare, for example.

Greenphire Travel Reimbursement program
Greenphire Travel Reimbursement program is providing payment for inconvenience fees and travel reimbursement. You are invited to voluntarily take part in this optional program to reimburse you for your study inconvenience fees and travel expenses. You do not have to participate or you can also decide to stop participating at any time.

Greenphire is offering Lyft transportation services. Please speak with study staff for more information.

More information about reimbursement is in the Study Participant Reimbursement Information Sheet.

Will I be paid to take part?
You will be provided an inconvenience fee for time spent (e.g., lost wages) and burden of the study. For visits 1, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20 and 801 you will receive $75 for each completed visit. Visits 2 and 3 are $100 for each completed visit. For completing visit 16 is $25. Should you need early discontinuation visits 1, 2 or early termination, they are $75 for each completed visit.

You may be reimbursed actual expenses for all study visits completed on the items indicated below:

- Transportation will be reimbursed at least the minimum standard IRS mileage rate for medical transportation to cover transportation from your home address to the nearest study treatment center at time of enrollment. The IRS mileage rate may change periodically.
- Public transportation (taxis, bus, train, subway). When mileage is NOT being paid, you will receive a flat rate for public transportation (bus, train, taxi, subway) for travel from your home address to the nearest study treatment center at time of enrollment not to exceed $100.00.
- Parking fees and tolls, if applicable. There is a $50 maximum limit per visit. You will be reimbursed the actual amount up to the maximum amount. Parking fees will not be reimbursed if the cost is covered by the site. Receipts or other supporting documentation are required if applicable/available.

• Meal reimbursement will be provided for: study visit 2 (up to 3 meals at $25 each); study visit 3 (up to 3 meals at $25 each); and 1 meal at study visits 6, 9, 15, 17, 19, 20 and 801 at $25 each. There is also 1 meal at study visits ED1, ED2 and ET at $25 each, if applicable.
• Hotel stay reimbursement for you may be provided at study visits 2 and 3. You will be reimbursed the actual amount up to the maximum amount determined by your location. Reimbursement may not cover the entire hotel rate. Receipts are required.

Note: The IRS requires that compensation (not documented by receipts or other tracking methods) greater than or equal to $600 be reported to the IRS as required by law. This IRS reporting will require you to provide your full Social Security Number. Refer to http://www.irs.gov/pub/irs-pdf/i1099msc.pdf for full details on the information that is included on the IRS Form 1099-MISC.

If you do not finish the study, you will be reimbursed for the part of the study that you did complete. However, your expenses could be more than the amount you are reimbursed.

What happens if I am injured because I took part in this study?
If you are physically injured, please seek medical help and call the study doctor immediately. The study doctor will provide medical treatment or refer you for treatment. Your insurance may be billed for this treatment. If you follow the directions of the study doctor and staff, the sponsor will pay the medical expenses for the treatment of a physical injury because of a properly given drug or procedures.

Who should I contact if there is an emergency or if I have questions?
Contact the study doctor or study staff at the phone number(s) listed above on the first page for any of the following reasons:

- if you have any questions about this study or your part in it;
- if you feel you have had an injury or bad reaction, or any other unusual health event; or
- if you have questions, concerns, or complaints about the research study.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888)-303-2224 or (800) 562-4789, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Will my medical information be kept private?
Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

The study doctor and staff will handle your personal health information in a confidential manner.

By signing the consent document for this study, you give permission ("authorization") for the uses and disclosures of your personal health information in the following ways.

- Your original medical records (which may contain your full name or other information that may directly identify you) and information created or collected during the research (This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.) may be shared with or viewed by to ensure the quality of the study conduct and study data, or for other reasons that are allowed under the law:
    - The sponsor of the study and its representatives "sponsor",
    - the regulatory authorities (such as the FDA) in this country and in other countries, and
    - The Institutional Review Board (IRB) that reviewed this research. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.

- Your study data (information collected for the study which only identifies you by a code and not your full name or other information that may directly identify you) may be shared with or viewed by:
    - the sponsor and their business partners (including those in other countries)
        - When the sponsor shares any data outside of this country, the sponsor will respect the terms of this data privacy statement even if other countries may have privacy laws that do not provide the same protections

        - The sponsor will only share your study data with their business partners, only if they need the information as a part of this work with the sponsor. The business partners must sign a contract that requires it to protect your study data in the same way as the sponsor.

    - the regulatory authorities (such as the FDA) in this country and in other countries,
    - the IRB overseeing this study, and
    - the doctors at other institutions participating in the study.

- The sponsor will use the study data:

    - to support the study purposes described in the consent document,
    - to determine how safe or effective any of the drugs or treatments included in the study,
    - to better understand the disease(s) included in the study, or
    - to improve the design of future studies.

- Study data that does not directly identify you may be published.

Your health information may be further shared by the groups above.Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by your study doctor to these other parties. These groups are committed to keeping your health information confidential.

You have the right to see and copy your personal health information related to the research study. However, you may not be able to review some of the study data until after the study has been completed to ensure the scientific integrity of the study.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

You may cancel your authorization for the uses and disclosures of your personal health information at any time by providing written notice to the study doctor. If you cancel your authorization:

- No new health information will be gathered unless you have a side effect related to the study.
- The study doctor and staff will only use or disclose some of your personal health information if it is needed to confirm the accuracy of the study data.
- The sponsor will still use and share study data that was collected before you cancelled your authorization.
- You will no longer be able to participate in the study.

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

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 otherwise entitled.

STATEMENT OF CONSENT

To become a part of this study, and to authorize use and disclosure of your personal health information, you must sign and date this page.

Only sign this consent after:

- You have read all of the information in this Study Participant Information and Consent Form and HIPAA Authorization, and you have had time to think about it.
- All of your questions have been answered to your satisfaction.

You voluntarily agree to be part of this research study, and to do the following:

- to follow the study procedures,
- to provide necessary information to the study doctor, nurses, or other staff members, as requested, and
- allow the study doctor and the sponsor to use and disclose your personal health information as described in this document.

You may freely choose to stop being a part of this study at any time. You will receive a copy of this signed Study Participant Information and Consent Form and HIPAA Authorization to keep.

FOR STUDY PARTICIPANT TO COMPLETE

Signature of Study Participant	Date (Study Participant must personally date)
Study Participant Name (print or type)	

FOR INDIVIDUAL CONDUCTING INFORMED CONSENT DISCUSSION TO COMPLETE

I have explained the study (such as the purpose, risks, benefits and the procedures) to the study participant before the study participant voluntarily agreed to participate.

Name of Individual Conducting Informed Consent Discussion (print or type)	
Signature of Individual Conducting Informed Consent Discusion	Date (Individual Conducting Informed Consent Discussion must personally date)