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SEPTEMBER 12, 2020

STUDY PARTICIPANT INFORMATION AND CONSENT FORM

NAME OF SPONSOR COMPANY:	Eli Lilly and Company
PROTOCOL NUMBER AND TITLE OF STUDY:	I8B-MC-ITSW; "A Study of LY900014 in Participants with Type 2 Diabetes using Continuous Glucose Monitoring"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Anuj Bhargava, M.D.
TELEPHONE NUMBER(S), DAYTIME & AFTER HOURS:	(515) 329-6800

INTRODUCTION

You are being asked to voluntarily be in a medical research study of a study drug known as LY900014. Eli Lilly and Company (Lilly) and its representatives ("sponsor"), are sponsoring this study and are paying the study doctor and/or study 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.

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WHY IS THIS STUDY BEING DONE?

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 question:

- Whether LY900014 can help study participants with type 2 diabetes keep glucose (sugar) levels in target ranges. The study insulin (LY900014) is a short-acting insulin that you take with meals.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 167 study participants will be taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

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

You can take part in this study if:

- You are 18 years or older
- You were diagnosed with type 2 diabetes at least 1 year ago
- You are already being treated with long-acting and mealtime insulins required for study participation
- Your blood glucose levels are within allowed limits for study participation
- You have a regular sleep/wake schedule (sleep at night and are awake during the day)

You cannot participate in this study if:

- You have had emergency treatment for very low blood glucose or very high blood glucose within the past 6 months
- You are taking certain diabetes medications that are not allowed for study participation.
- You have major problems with your heart, kidney, liver, or you have a blood disorder.
- You have had or are now being treated for certain types of cancer.

It is important that you are completely truthful with the study staff about your health history. If you are not honest about your health history, you may harm yourself by participating in the study. You should not take part in this study if you do not meet all requirements.

If you choose to be a part of this study, you will be involved for around 4 months. The entire study will last around 18 weeks and is made up of the following segments:

1 week screening period
The study doctor will determine if you can participate in the study.

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4 week baseline period

- You will receive diabetes education and nutrition counseling
- You will be trained on the study procedures and equipment, including completion of your paper study diary to collect insulin dosing information.
- You will be trained on and given a continuous glucose monitoring system (CGM) to use during the study to monitor your glucose levels. The Freestyle Libre CGM has a sensor that you will wear on your arm, which is scanned by the reader to collect your glucose readings. The sensor can be worn for up to 14 days. The sensor should be changed every 14 days or earlier, if needed per the package instructions.
  - Data from the CGM reader will be transferred by your site through a secured database. This data will not contain any personal information that could identify you.
  - The sensor must be removed before magnetic resonance imaging (MRI), computed tomography (CT) scan, X-ray, or high frequency electrical heat (diathermy) treatment.
  - You may be asked to try to avoid medicines that may interfere with sensor glucose readings such as higher doses of vitamin C and/or higher doses of some pain relievers that include aspirin.
- FreeStyle Libre CGM Reader:
  - You will use the reader to scan the CGM sensor.
  - **You will be asked to bring your reader to every study office visit.**
  - The reader will be used to collect glucose data for the study.
  - The reader also has a built-in fingerstick blood glucose (sugar) test strip port for you to check your blood glucose if needed. Blood glucose test strips for use with the reader will be provided through the study.
- Study Mobile Device, Study Email and LibreLink Application (app):
  - You will be given a mobile device for use during the study, equipped with the LibreLink Application (app), as well as an app to access a study email account.
  - The LibreLink (app):
    - During the study, you will use the app to scan the CGM sensor in addition to the CGM reader.
    - This app allows your study doctor to review your glucose data and to adjust insulin dosing during telephone visits without you having to come into the study doctor's office.
    - You will be able to review your glucose levels with the Librelink app and/or the reader to take care of your diabetes.
      - The study sponsor will not have access to the Librelink App.
      - In order to set-up your LibreLink App, an email account is required. Study staff will help you to set up a study-specific email account during visit 2. The mobile device and email account should only be used for the study.
- You will scan the sensor with both the reader and app at least 4 times throughout the day (morning upon waking, prior to meals, at bedtime) during the baseline period. You may scan more than 4 times a day, and more frequent scanning is encouraged. Make every effort to scan with the reader and app at least every 8 hours to avoid gaps in glucose data.
  - **Initial Scans following application of a New Sensor:**
    - Start each new sensor session by Scanning the sensor with the CGM reader **first**, and then scanning with the mobile device via the LibreLink app.
    - After the start of a new sensor session, the sensor can be scanned with the reader and app in any order.

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- You will continue your usual pre-study long-acting insulin and short-acting insulin with meals during the baseline period. In addition, you may also continue up to 3 allowed tablets or pills and an allowed injection for diabetes treatment during the study.

12 week treatment period

- At visit 4, you will stop your pre-study insulins and will start taking the study provided insulins (LY900014 and insulin glargine U-100 (Basaglar)) for 12 weeks.
- You will use pre-filled pens for insulin injections. The study staff will provide instructions for injections of study-provided insulins.
- You will be asked to inject LY900014 within 0 to 2 minutes with your 3 main meals each day (breakfast, lunch and evening meals) between visits 4 and visit 12.
  - There are two options for your mealtime insulin dosing:
    - Carbohydrate counting: If you were counting carbohydrates in your meals to dose your short-acting insulin before enrolling in the study, you may continue this with LY900014 during the study.
    - Fixed-dose: If you were taking fixed doses of short-acting insulin with meals before enrolling in the study, you will receive instructions from the study doctor on how to gradually adjust the dose of LY900014 until your glucose levels are within the goal range
- You will scan the CGM sensor with both the reader and app at least 4 times throughout the day (morning upon waking, prior to meals, at bedtime) during the 12 week treatment period. You may scan more than 4 times a day, and more frequent scanning is encouraged. Make every effort to scan with the reader and app at least every 8 hours to avoid gaps in glucose data.
- The study doctor will review your glucose levels from the study CGM and will discuss insulin dosing with you during your clinic and telephone visits. Your study doctor may adjust your insulin doses depending on how your body responds.

2 week follow up period

- Upon completion of the study treatment period, your study doctor will discuss insulin and other diabetes treatment options available to you. The study doctor will monitor your health.

You will:

- use the study drug only as instructed by the study staff;
- be asked to agree to the terms of use required to set-up a Librelink App account, your study email account, and your study mobile device.
- bring your CGM reader and completed paper study diary to each study office visit. During the telephone visits, you should also have your CGM reader and mobile device and the paper study diary available to discuss with the study doctor or study nurse.
- return any unused study drug at the end of this study, or as instructed by the study staff;
- return all study equipment including unused CGM sensors, CGM reader, and study mobile device when your participation in the study ends

While participating in this study, you should not donate blood or blood products, or make any major changes to diet and exercise.

The schedule of events is included below. This will give you information about what will happen at each specific visit and how often the procedures will happen.

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	Screening Visit	Baseline		On the Study Drug									Follow-up Visit	ED	Comments
Visit Number	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	**Visit 11**	**Visit 12**	**801**	**ED**	
Study Weeks				**0**	**1**	**2**	**4**	**6**	**8**	**10**	**11**	**12**	**14**		
Phone Visit (grey shaded)			**X**		**X**	**X**		**X**		**X**	**X**		**X**		Phone visits may be conducted as office visits, if needed.
Estimated Time Between Study Visits	**Up to 5 weeks prior to V4**	**Up to 4 weeks prior to V4**	**Up to 2 weeks prior to V4**	**0 days**	**1 week**	**2 weeks**	**4 weeks**	**6 weeks**	**8 weeks**	**10 weeks**	**11 weeks**	**12 weeks**	**14 weeks**		
Estimated Visit Length (hours)	**1.5**	**2**	**0.25**	**2.25**	**0.25**	**0.25**	**1.5**	**0.25**	**1.5**	**0.25**	**0.25**	**1.5**	**0.25**		
Procedures:															
Sign an informed consent form	**X**														

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Talk with study staff about your health, what medications you have taken and what you are taking now	**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. The study doctor may ask you about preexisting conditions.
Have a physical exam/Height	**X**														
Collect weight and vital signs	**X**	**X**		**X**			**X**		**X**			**X**		**X**	Vital signs include heart rate, blood pressure and body temperature
You will be asked about drug and alcohol abuse history	**X**														
Diabetes, Hypoglycemia and Nutrition Counseling		**X**													*May be repeated at subsequent visits

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You will receive Study Devices: CGM reader and mobile device with pre-loaded CGM LibreLink app		**X**													
You will receive study device training		**X**													
You will receive study supplies, and paper diary to collect insulin dosing information		**X**		**X**			**X**		**X**						
You will receive training on paper diary		**X**													
You will return paper diary to study doctor				**X**			**X**		**X**			**X**		**X**	
You will receive LY900014 and Basaglar®				**X**			**X**		**X**						
Have blood drawn – approximate amount in mL (and teaspoon)	**6 (1.2)**			**2 (0.4)**			**2 (0.4)**		**2 (0.4)**			**2 (0.4)**		**2 (0.4)**	

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You will take a pregnancy test (if applicable)	**X**			**X**											By a blood test at visit 1, by a urine test at visit 4 and at other visits if needed.
Have an Electrocardiogram (ECG)	**X**														
Complete questionnaires		**X**		**X**								**X**		X	
You will return unused study drug							**X**		**X**			**X**		X	
You will return study mobile device, CGM reader												**X**		X	

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Abbreviations: CGM=Continuous Glucose Monitoring; ECG = electrocardiogram, ED = Early discontinuation

Due to several recent measures to limit the spread of disease in the case of a pandemic, there may be restrictions on travel, public transportation, and access to hospitals and clinics in your area during this study. In anticipation of this possible situation, local blood draw services contracted through LabCorp, have been setup and may be used to support the laboratory collections/assessments for certain study visit(s) instead of actual in-person office visit(s). This remote service, if used, will require access to your personal information and will be requested through a centralized Patient Service Call Center in combination with your site as applicable. You will also be required to contact the patient Service Center to schedule the appointment and provide a personal mailing address for shipping of instructions and for identifying convenient blood draw location. However, this personal information will not be shared outside of the requirements for the study. Please review the LabCorp privacy details located on the following website: www.labcorp.com. Prior to using this blood draw service, your study staff will explain the process in more detail.

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 at your study doctor's discretion, to confirm your safety or 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.

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 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.

In addition, blood or urine samples may be tested for alcohol or drugs during the study. You will be given the test results and may be asked to stop taking part in the study.

Blood samples may be tested for hepatitis A, B, C, D and/or E which are serious and contagious diseases. If your test results are positive, your study doctor or staff will contact you.

The results of alcohol or drug screen, hepatitis A, B, C, D and/or E testing will be kept confidential and disclosed only as required by law.

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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
In the rare case where you have an allergic reaction, blood and urine samples may 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 Antibody Research
In the rare case where you have an allergic reaction, blood sample(s) may 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.

Your information or bio-specimens will not be used or distributed for future research studies even if identifiers are removed.

WHAT WILL HAPPEN WHEN I AM FINISHED WITH THE STUDY?

The study doctor or their staff may discuss treatment options for you after your participation in this study has ended.

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.

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

<u>Risk Profile for study insulin (LY900014)</u>

Lilly regularly reviews all important safety information for their study drugs.

As of 30 April 2019, in the completed and ongoing studies, approximately 2111 healthy volunteers and patients with diabetes have received LY900014.

Like other insulin products, the most common risk with LY900014 is low blood sugar, which could cause lack of energy, hunger, confusion, pounding heart, sweating, shakiness, and headache. Low blood sugar may occur overnight. Patients may also have a blood sugar low enough that they cannot treat themselves. Severe cases of low blood sugar could cause seizures, unconsciousness and, in extreme cases, death.

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Occasionally, patients taking any insulin, including LY900014, may experience weight gain, swelling due to fluid retention, or pain, redness, swelling, or itching where the insulin is injected. Rarely, a dimple or depression in the skin or an enlargement or thickening of the tissue under the skin may form over time if the insulin, including LY900014, is always injected in the same place. Patients taking any insulin, including LY900014, may experience a generalized allergic reaction, a very rare but possibly life-threatening event.

ADDITIONAL PROCEDURE RISKS

Risks of Insulin Injection via Pre-Filled Pens
During the study, LY900014 and Insulin Glargine U-100 will be provided as prefilled pens for injection. You must read the entire "Instructions for Use" before using the pens, and you must carefully follow the directions. If you do not follow the directions provided with the pen, or if you use the pen incorrectly, you may receive too much or too little insulin. This may result in either low or high blood glucose. If any part of the pen looks like it is damaged or broken, you should not use the pen, and should return it to your study doctor. A pen that does not work properly may deliver too much or too little insulin, even if the directions are followed exactly. The choice of delivery system will not affect risks described for insulin. Please talk to the study doctor or staff about any questions or concerns that you may have about the procedures required for this study.

Risks of the Freestyle Libre CGM System
Applying the sensor and wearing the adhesive that keeps the sensor attached to your skin may cause mild skin irritation such as redness, bruising, bleeding, infection, or a small bump in the skin. The chance of this happening is low.

The sensor must be removed before magnetic resonance imaging (MRI), computed tomography (CT) scan, X-ray, or high frequency electrical heat (diathermy) treatment.

Glucose Monitoring
Blood glucose (or 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.

Risks for Subcutaneous Injections (SC)
For most people, needle punctures for SC shots do not cause any serious problems. Sometimes they may cause bleeding or bruising where the shot is given. Sometimes people complain of discomfort, infections and/or pain at the site of the shot. Infection may happen with SC shots because the needle breaks the skin. Then germs can get into the skin underneath. Shots may cause abscesses or skin and soft tissue infections. Additionally, if a blood vessel is hit by the needle, the risk of infection will be even greater if germs are taken into the blood system.

Allergic Reaction or Antibodies to Insulin Injections
Over time, you may also develop a reaction to taking insulin. It could interfere with how your body reacts to insulin. This could lead to low or high blood sugar, which would require insulin dose adjustments. Rarely, you may have an allergic reaction which may be life-threatening.

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

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Risks of Blood Tests

For most people, needle punctures for blood draws do not cause any bad problems. However, sometimes they may cause redness, bleeding, bruising, discomfort, infections, pain, nerve damage or blood clots (which may cause inflammation, swelling and pain) where you had the blood drawn. You may also feel dizzy or pass out.

Other Risks

In addition to the side effects already described, LY900014, and other drug(s) required by this protocol 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.

Long-acting insulin glargine U-100 (Basaglar or LY2963016) is being given to you in this study.

Insulin Glargine U-100 (Basaglar or LY2963016)

As of 21 April 2019, cumulative patient exposure of insulin glargine (LY2963016) totaled 1507 patients.

LY2963016 is an insulin product, approved for the treatment of diabetes. LY2963016 is highly similar (biosimilar) to another product that is already available on the market, called LANTUS® (insulin glargine, Sanofi-Aventis, Bridgewater, NJ). LY2963016 is a kind of insulin with the same active ingredient found in LANTUS®. LY2963016 and LANTUS® are made using different methods. This could result in slight differences between the 2 products overall. LY2963016 is expected to work in the same way and have the same effect in people as LANTUS®. LANTUS® has been used for over 13 years in people with diabetes to lower blood sugar. The effects of LANTUS® can last for up to 24 hours. Because LANTUS® lasts for a long time, it lowers blood sugar level for a longer period of time than short-acting insulins.

A common experience reported by those taking any insulin, including LY2963016, is low blood sugar, which could cause lack of energy, hunger, confusion, pounding heart, sweating, shakiness, and headache. Low blood sugar may occur overnight. Patients may also have blood sugar low enough that they cannot treat themselves. Severe cases of low blood sugar could cause unconsciousness, and in extreme cases, death.

In clinical studies comparing LY2963016 and LANTUS® in patients with type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM), the side effects of the 2 drugs were shown to be highly similar. These side effects are described in Table 1. No new side effects were seen in the clinical studies with LY2963016.

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Table 1. Unpleasant Reactions Seen with LANTUS® or LY2963016

Very Common (10 or more out of 100 patients)	Common (1 or more out of 100 patients)	Uncommon (1 or more out of 1000 patients)	Rare (1 or more out of 10,000 patients)	Very Rare (less than 1 out of 10,000 patients)
Low blood sugar	Thickening of skin tissue	Thinning of skin tissue	Allergic reactions	Loss of taste
	Redness, pain, swelling, or itching at injection site		Swelling	Muscle pain
			Problems with eyesight	

Source: LANTUS® Summary of Product Characteristics.

There may be redness, pain, swelling, itching, or hives where the insulin is injected. Pain where the insulin is injected happens in about 3 out of every 100 people who take LANTUS®. Sometimes, a dimple or thickening in the skin can form over time if you always inject in the same place. To help prevent these side effects, change where you inject your insulin each time.

As with other insulins, your body's immune system (disease-protection system) may react to LY2963016 by making proteins (antibodies) that react with foreign substances in your body. Antibodies formed against LY2963016 could cause an allergic reaction or could interfere with how the body normally responds to insulin (insulin resistance). Blood samples may be taken in some studies to see if antibodies to LY2963016 are being formed. Patients taking any insulin, including LY2963016, may experience a generalized allergic reaction to insulin, a very rare, but possibly life-threatening event.

You can inject insulin using a syringe or a pen-type device. If you use a pen-type device, you must read the instructions provided before using the pen. You must also carefully follow the directions. If you do not follow the directions that come with the pen, or if you use the pen incorrectly (which may result in a broken, damaged, or jammed pen), you may receive too much or too little insulin. This may result in low blood sugar or high blood sugar. If any part of the pen looks like it is damaged or broken, do not use the pen and return it to your study coordinator. A pen that does not work properly may deliver too much or too little insulin, even if you follow the directions exactly. The choice of a syringe or pen will not change the risks described for insulin.

Sometimes, other medicines you are taking can affect how well LANTUS® or LY2963016 works to lower your blood sugar. Your study doctor will tell you what drugs can be taken while taking LY2963016. Be sure to tell your study doctor about all medicines, even over-the-counter medicines (medicines you can buy without a prescription) you are currently taking.

Insulin treatment can cause you to gain body weight. This side effect is expected with both LANTUS® and LY2963016.

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Many people can treat their low blood sugar levels by themselves. This can be done by drinking or eating a food with carbohydrates ("carbs"). Severe low blood sugar is a situation in which a person cannot treat low blood sugar by himself or herself. That is, another person needs to help treat the severe low blood sugar level. Severe low blood sugar level was seen in 7 out of 100 adults with T1DM taking LANTUS® and insulin lispro for 16 weeks. Severe low blood sugar level was seen in 11 out of 100 adults with T1DM taking LANTUS® and regular insulin for 28 weeks. Severe low blood sugar level was seen in 23 out of 100 children with T1DM taking LANTUS® and regular insulin for 26 weeks. In patients with T1DM, about 3 out of 200 patients taking LY2963016 and insulin lispro had an episode of severe low blood sugar level over 24 weeks.

Severe low blood sugar level was seen in about 2 out of 100 adults with T2DM taking LANTUS® and oral agents for up to 1 year. Severe low blood sugar was seen in about 8 out of 100 adults taking LANTUS® and regular insulin for 5 years. In patients with T2DM, about 1 out of 200 patients taking LY2963016 and oral agents had episodes of severe low blood sugar level over 24 weeks.

Risks in Pregnant, Breastfeeding Mothers, Children, and Older Population

LY2963016 has not been studied in pregnant animals. The effects of LY2963016 in pregnant animals should be similar to other kinds of insulin, including LANTUS®. Birth defects have been found in baby animals when mothers were treated with other kinds of insulin during pregnancy. These birth defects are thought to be due to severe low blood sugar episodes in pregnant animals getting other kinds of insulin. More modest doses of other kinds of insulin produced less severe and temporary decreases in blood sugar. These more modest doses did not cause birth defects. There are no clinical studies of the use of LANTUS® in pregnant women.

Pregnant or breastfeeding mothers are not planned to be included in studies with LY2963016. If you are pregnant or plan to become pregnant during the study, you should not participate in the study. Women who are able to conceive a child should use birth control methods approved by their study doctor during clinical studies. You should not become pregnant or breastfeed while taking part in this study. Please refer to the section of this consent form entitled **"BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING"** for more information.

The safety of LANTUS® has been studied in children aged 2 years and above. Different countries have approved LANTUS® to be used in children of different ages. For example, in the United States, LANTUS® and LY2963016 have been approved to be used in children with T1DM aged 6 to 15 years. In the European Union (EU), LANTUS® and LY2963016 have been approved to be used in children 2 years or older. LANTUS® is as safe as neutral protamine Hagedorn (NPH) insulin, an intermediate-acting form of human insulin, when given along with regular insulin or with rapid-acting insulin.

In studies in patients who were taking LANTUS® or NPH insulin, patients older than 65 years had more events involving the heart and blood vessels than the population as a whole.

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BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

There may also be unknown risks to your embryo, fetus, or breastfeeding child. 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 study doctor about the types of birth control that are best for you and your partner. Tell your study doctor right away if you become pregnant or think you are pregnant.

You are not required to use contraception if you are a woman in (an) exclusively same-sex relationship(s).

Even if you use birth control during the study, there is a chance you could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug or procedure may involve unforeseeable risks to the unborn baby. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot be in the study if you are breastfeeding. It is not known whether the study drug is safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not receive any benefit from being in this study. If you take part in this study, other people with type 2 diabetes may be helped.

Information obtained from this study may also benefit the sponsor of the study and may benefit study participants in the future. You may receive information from physical examinations, laboratory tests, or other testing that is done in this study, but these tests may not have any impact on your health.

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 type 2 diabetes. Other treatments are available, including other short-acting insulins. Your study doctor can talk with you about other options you have to treat your type 2 diabetes.

ADDITIONAL INFORMATION

Study Device Usage

- You will not be able to use a personal Librelink app account with the CGM device provided for this study
- You will not be able to use a personal email account to create your Librelink app account.
- Your study email address should only be used for the following study purposes:
  - to set-up your account through the LibreLink App
  - for password resets, as needed
- Personal emails should not be sent from your study email account.
- Use the mobile device only as instructed by study staff.
- No personal information should be shared on the study mobile device. Any data located on the mobile phone could be retrievable by the sponsor.

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- At visit 12 (or early discontinuation visit), you will be asked to return the mobile device, unused sensors for the CGM device, and CGM reader to the study staff as soon as possible. You may not retain these devices for personal use. Study devices will be wiped of all data and de-activated once your participation in the trial ends.
- Data from the mobile device will be shared with your study doctor. If you continue to use the mobile device after you finish participating in the study, then the data will continue to go to your study doctor until you stop using the mobile device and return it to the study doctor's office.
- If you continue to use the CGM reader after you finish participating in the study, then the data will be transferred when the reader is returned to the site.
- Therefore, it is highly recommended that you return the mobile device and CGM reader when you finish participating in the study. Any data that you provide after you finish participating in the study will be included in data collection and in the overall results if applicable.

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, sponsor, IntegReview, or the FDA, if applicable, for any reason without your consent for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If this happens, it might be due to a bad reaction you have to LY900014 or insulin glargine U-100 or new information about the drugs' safety or effectiveness.

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. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Study drug and study procedures will be provided at no cost to you.

You and/or your health insurance may be billed for the routine costs of medical care provided during this study. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should contact your insurance company for more information or check with the study doctor if you have any questions about this.

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You may have to pay for some expenses related to this study. You will be provided study inconvenience fees and travel expenses. 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 you are reimbursed.

You are invited to voluntarily take part in an 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.

You will be provided a fixed amount $50.00 per study visit for inconvenience fees for clinic visits at visits 1, 2, 4, 7, 9, and 12. You will be provided a fixed amount of $25.00 for inconvenience fees for phone visits at visits 3, 5, 6, 8, 10, 11 and visit 801.

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). 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. You will be reimbursed the actual amount up to the maximum amount per round trip visit. Car rental is not included in this coverage. Receipts are required.
- Parking fees and tolls, if applicable. There is a $50.00 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.

If you choose to leave or are withdrawn from the study for any reason before finishing all visits, you will be paid for each completed visit. You will receive payment at the end of each study visit.

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. Refer to http://www.irs.gov/pub/irs-pdf/i1099msc.pdf.

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

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you are injured, please seek medical help. 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.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

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WHO SHOULD I CONTACT IF THERE IS AN EMERGENCY OR IF I HAVE QUESTIONS?

Contact the study doctor 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
- If you have questions, concerns, or complaints about the research study

Anuj Bhargava, M.D.
(515) 329-6800 - daytime and after hours telephone number

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

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WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

The study doctor and staff will handle your personal health information in a confidential manner, except when ordered by law.

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) may be shared with or viewed by the following to ensure the quality of the study conduct and study data:
  - The sponsor of the study and its representatives "sponsor",
  - the regulatory authorities in this country, including the FDA or other state or federal regulatory agencies, and in other countries, and
  - the ethical review board overseeing this study.
- 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 in this country and in other countries,
  - IntegReview IRB
  - 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 are 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 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.

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.

Your authorization for the uses and disclosures of your personal health information does not have an expiration date.

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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:

- 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 study data that was collected before you cancelled your authorization.
- You will no longer be able to participate in the study.

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Study Participant Information and Consent Form
Signature Page

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 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 and dated Study Participant Information and Consent Form to keep.

FOR STUDY PARTICIPANT TO COMPLETE

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

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
mjc/master: 7-29-20 mjc/master: 8-12-20 sab/site: 9-12-20

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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 Discussion

Date
(Individual Conducting Informed Consent Discussion must personally date)