Study Participant Information and Consent Form

Sponsor / Study Title:	**Eli Lilly and Company / "Efficacy and Safety of Tirzepatide Once Weekly in Participants with Type 2 Diabetes Who Have Obesity or Are Overweight: A Randomized, Double-Blind, Placebo Controlled Trial (SURMOUNT-2)"**
Protocol Number:	**I8F-MC-GPHL**
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Introduction

You are being asked to voluntarily be in a medical research study of a study drug known as Tirzepatide (LY3298176). Eli Lilly and Company and its representatives ("sponsor"), are sponsoring this study and are paying the study doctor and/or the 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 study 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 and date 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 Study 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. 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?

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 tirzepatide (LY3298176) can help study participants with Type 2 Diabetes Mellitus (T2DM) achieve and maintain weight loss

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) with obesity or overweight. Investigational means that the study 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 FDA is allowing the use of this drug for research.

How many people will take part in the study?

Approximately 900 study participants will be taking part in this study.

What will happen during the study?

You will be asked to:

- Sign and date 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.

You can take part in this study if:

- You are at least 18 years of age and age of majority per local laws and regulations.
- Have a body mass index greater than or equal to 27 kg/m2.

- Have a diagnosis of T2DM.

You cannot take part in this study if:

- You have certain serious medical conditions or a history of certain serious medical conditions other than obesity or T2DM, which your study doctor will discuss with you. This may include Type 1 diabetes mellitus, certain serious diabetes-related conditions, serious/active infections, certain cardiovascular problems, certain types of cancer, blood diseases, psychiatric disorders, or serious problems with your stomach, intestine, liver, pancreas, thyroid, or kidneys.
- You have taken certain medicines or had certain treatments, which your study doctor will discuss with you.
- You are pregnant or breastfeeding.

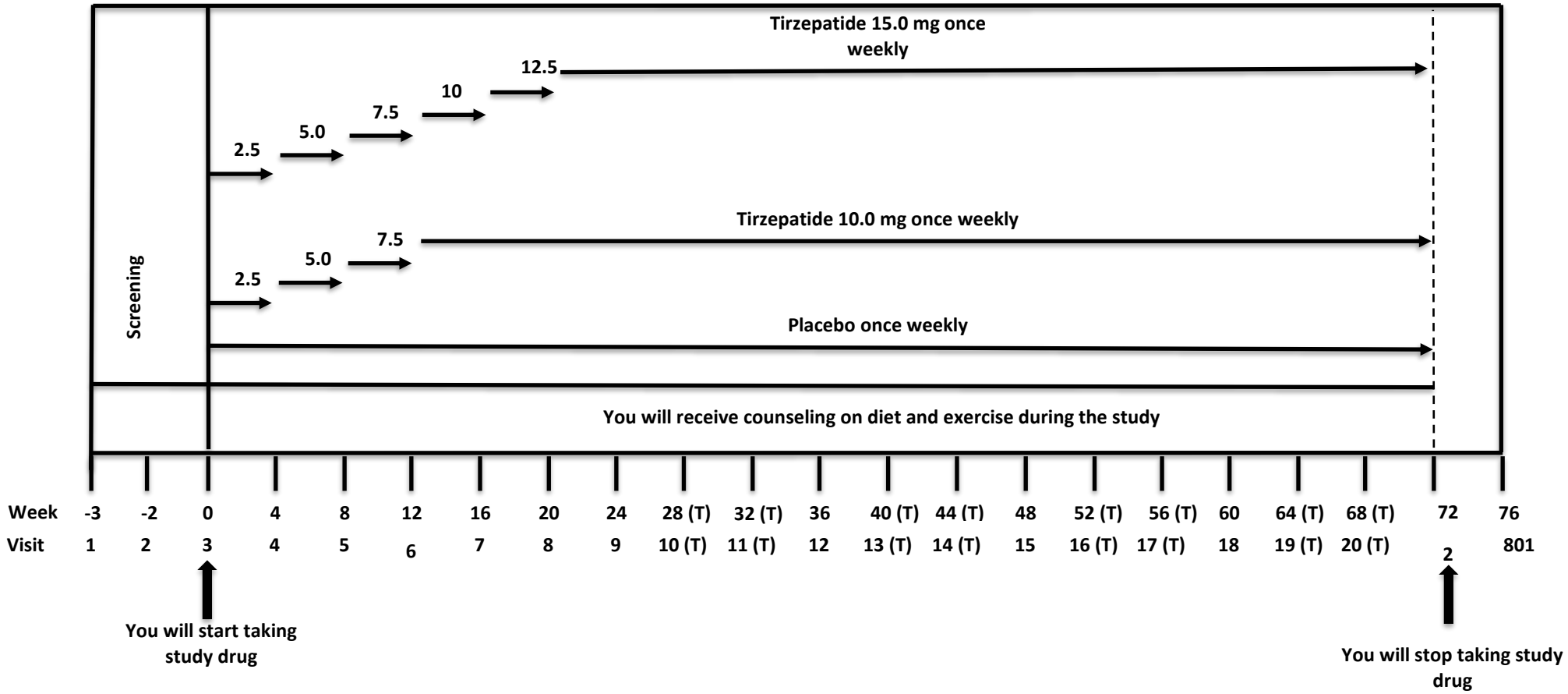
You may need to have some exams or tests done to find out if you are a candidate to begin the investigational drug. Some of these tests may be done even if you do not join the study as part of your normal care.

You will be screened to see if you qualify to be in this study. The screening period will last about 3 weeks.

At Visit 3, participants will be randomly divided into groups. You will receive either tirzepatide (LY3298176) (10 mg or 15 mg) or placebo. Placebo is a solution that looks like the study drug but has no medicine. Neither you nor the study doctor will know if you are taking tirzepatide or placebo. Whether you receive once-weekly injections of tirzepatide or placebo will be determined by chance. The chance that you will get tirzepatide is 2 in 3.

The study drug is given as an injection under your skin that is called a subcutaneous (SC) injection. The study staff will train you on how to give yourself injections at home. This study treatment period will last about 72 weeks, and will include a 20-week ramp-up period where the amount of study drug is increased slowly to help your body get used to the study treatment. A safety follow-up visit 4 weeks later will be your last visit.

Study Figure for GPHL



Abbreviation: (T) = telephone visit.

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
- give yourself the study drug by subcutaneous injection (under the skin)

It is important that you are completely truthful with the study staff about your health history. 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 about 79 weeks, including screening period, study treatment periods, and follow up period. You will have about 14 clinic visits and about 8 telephone visits.

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.

Study Schedule for GPHL

Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	99	ED	801
Week of Study Treatment	**-3**	**-2**	**0**	**4**	**8**	**12**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52**	**56**	**60**	**64**	**68**	**72**	**72**		**4 wks post end of TxP**
Fasting Visit	X		X	X	X	X	X	X	X			X			X			X			X	X	X	X
Telephone Visit										X	X		X	X		X	X		X	X				
You will sign and date an informed consent form	X																							
You will talk about your medical history	X																							
	Medical history includes assessment of preexisting conditions (for example, history of gallbladder disease, cardiovascular disease, and medullary thyroid carcinoma) and substance usage (such as alcohol and tobacco).																							
You will talk about how you feel, what medicine(s) you are taking, and discuss the study drug	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
You will have your weight, height, blood pressure, waist circumference, and/or pulse rate measured	X		X	X	X	X	X	X	X			X			X			X			X	X	X	X
You will have an eye exam		X																						
You will have a physical exam	X																							
You will have an electrocardiogram			X						X												X		X	X
			X	X	X	X			X			X			X			X			X		X	

Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	99	ED	801
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Fasting Visit	X		X	X	X	X	X	X	X			X			X			X			X	X	X	X
Telephone Visit										X	X		X	X		X	X		X	X				
You will receive Lifestyle Program instruction	You will receive counselling on diet and exercise, which will be performed by a dietician (or equivalently qualified person), to include calculation of individualized energy requirement and methods to change dietary composition and amount of physical activity. The Lifestyle Program Instruction may be delivered on a separate day from the rest of that visit's study procedures but must occur within the visit window. Beginning at Week 8, the consultation may be delivered by phone.																							
You will review your diet and exercise goals			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	
You will receive diabetes education, including self-injection with the auto-injector and use of the blood glucose meter		X																						
You will be given a blood glucose meter and supplies as needed		X	X	X	X	X	X	X	X			X			X			X			X		X	
Seven-point self-monitoring of blood glucose (SMBG) to be taken between this visit and the next visit		X						X												X				
	Record your blood glucose level before breakfast, 2 hours after breakfast, before lunch, 2 hours after lunch, before dinner, and 2 hours after dinner, and at bedtime. Study staff or the study doctor will explain this to you in detail.																							
You will be given a paper diary and instructed on its use		X	X	X	X	X	X	X	X			X			X			X			X		X	
	Bring your diary with you to appointments at the study site and be prepared to review it during phone visits.																							
You will answer questions about your lifestyle and physical and mental health	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	

Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	99	ED	801
Week of Study Treatment	**-3**	**-2**	**0**	**4**	**8**	**12**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52**	**56**	**60**	**64**	**68**	**72**	**72**		**4 wks post end of TxP**
Fasting Visit	X		X	X	X	X	X	X	X			X			X			X			X	X	X	X
Telephone Visit										X	X		X	X		X	X		X	X				
You will give a blood sample (approximate amount in mL) Note: 5 mL = 1 teaspoon	12		54	13	3	40	3		45			8			38			5			45		45	45
Pregnancy test for women of childbearing potential	X		X			X			X			X			X			X			X		X	
	By a blood test at Visit 1; by a urine test at all other visits. Additional pregnancy tests (beyond those listed here) should be performed at any time during the study if a menstrual period is missed, there is clinical suspicion of pregnancy, or as required by local law or regulation.																							
You will be given the study drug to take home with you			X	X	X	X	X	X	X			X			X			X						
Bring study drug and injection supplies with you to the study site			X	X	X	X	X	X	X			X			X			X			X		X	

Abbreviations: ED = early discontinuation; wks = weeks; TxP = study treatment period.

Additional Information

As a study participant, you will receive lifestyle counseling throughout the entire study. Lifestyle counseling will consist of advice on healthy food choices and focus on calorie restriction. You will also set exercise goals. Diet and exercise goals established during the lifestyle consultations and adherence to the lifestyle component of the study will be expected. You may be given a paper log to help you track your food and exercise. You will also be given a blood glucose monitor and trained on how to use it.

Meals/Diet – You will have to fast for at least 8 hours prior to each office visit and report to the study site.

Study Drug – During the study, you will be trained on how to inject study drug and should be willing to self-inject or have the assistance of a trained person who will inject the study drug if needed (for example, visual impairment or physical limitations make self-injecting not possible).

Paper Study Diary – You will use a paper study diary as instructed by the study staff. You will use the diary to record your weekly study drug dose injections and low blood glucose events. You will bring the paper study diary to every study visit.

Blood glucose monitoring – During the study, you will be provided study supplies that are needed for the study procedures: a blood sugar monitoring device and testing strips. You will also be trained on diabetes self-management.

You may be asked to provide your ethnicity and race. You do not have to provide this information if you would prefer to keep it private.

During the study, you should not start any other treatment for weight loss, including prescription or over-the-counter medicines, supplements, formal weight loss programs outside of the study, weight loss devices, or bariatric surgery that would make it difficult to interpret the effect of the study drug on your weight. Do not donate blood or blood products during the study.

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 study staff.

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.

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/RNA. DNA/RNA is genetic material that is found in all the cells of your body. DNA/RNA 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/RNA can sometimes help explain why people with a disease respond differently to the same medicine. For example, some people taking this study drug may respond well. Others may have little or no response, or have side effects.

Researchers may study your DNA/RNA to learn how the study drug works for you. Information about your DNA/RNA may be used to create or improve tests to measure these genetic factors. Researchers may also study your DNA/RNA to better understand obesity. The DNA/RNA 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 obesity 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.

What will happen when I am finished with the study?

The study doctor or one of the study staff members may try to reach you after you have stopped study treatment. You will not receive the study drug after your completion of the study. They will also ask you to return for an additional visit for the purpose of body weight measurement, and 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 study staff, they may give your name and last known contact information to a patient locator service to try to find your current information, if not prohibited by your local laws and regulations. The patient locator service will not contact you directly and any new information they find will be shared with the study doctor and study staff.

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.

As of 15 June 2018, 338 adults with type 2 diabetes (T2DM) and 67 healthy adults have taken tirzepatide (LY3298176) in completed studies. Many of these participants were considered to be overweight or obese. Lilly (the sponsor) has reviewed safety information from these studies.

The following table lists the risks and discomforts associated with LY3298176 for participants with T2DM.

Table 1.

Very Common (10 or more out of 100 participants)	Feeling sick to the stomach Loose or frequent stools Throwing up, vomiting Loss of appetite	
Common (1 or more out of 100 participants)	Headache Dizziness Indigestion Heartburn Feeling tired, fatigue Hard or infrequent stools	Passing gas Bloating Belching Stomach pain or discomfort Weight loss Low blood sugar
Uncommon (1 or more out of 1000 participants)	Feeling full quickly when eating	

Cases of pancreatitis have been reported in participants with T2DM who have taken LY3298176 and other glucagon-like peptide-1 receptor (GLP-1) medicines. Pancreatitis is an inflammation of the pancreas, a gland in your abdomen that helps with digestion. Pancreatitis is usually associated with stomach pain, which may be severe. Although pancreatitis usually improves without long-term effects, it may be severe and could lead to hospitalization or even death.

If you develop abdominal pain that is not normal for you, or if you develop severe nausea with or without vomiting, you should call your study doctor immediately for evaluation and proper care. If you have pancreatitis symptoms or if routine laboratory tests suggest a need for evaluation, you may be asked to return to the study site for further evaluations, which may include additional blood tests, X-rays, or other abdominal pictures.

Symptoms of nausea, vomiting, and diarrhea may lead to loss of fluids (dehydration). The loss of fluids could worsen kidney function, which includes kidney failure, and requires immediate evaluation by the study doctor for appropriate care.

Tirzepatide (LY3298176) is not recommended for participants with severe stomach problems, such as slowed emptying of the stomach (gastroparesis) or problems with digesting food.

Increases in resting heart rate (HR) above the normal range (more than 100 beats per minute) have been seen in both healthy subjects and participants with T2DM taking LY3298176. Increased HR can have no symptoms or symptoms such as pounding heart, irregular or "skipped" heartbeat that you can feel, chest pain, or other more severe symptoms. Your HR,

blood pressure, and electrical recordings of the heart (electrocardiograms) may be checked regularly.

If you take LY3298176 with or without other medicines used to treat T2DM, your blood sugar could become too low (hypoglycemia). While taking LY3298176, you may be more likely to have low blood sugar if you are also taking insulin or an insulin secretagogue (sulfonylurea). It is important to follow the study doctor's recommendations for monitoring your blood sugar level during your participation in this study. You should tell the study doctor if you experience any symptoms of low blood sugar, such as sweating, hunger, shakiness, or confusion.

Cases of severe and potentially life-threatening allergic reactions have occurred rarely in people taking other GLP-1 medicines and may be a potential side effect with LY3298176. LY3298176 should not be given to participants who have had a serious allergic reaction to LY3298176 or any of its ingredients.

Your body's disease protection system (immune system) may react to LY3298176 by making antibodies. Your study doctor may take blood samples during the study to check for antibodies to LY3298176.

Very rarely, cases of medullary thyroid cancer were reported with other GLP-1 medicines. If you or anybody from your family (genetic relatives only) have had this type of cancer or another disease called multiple endocrine neoplasia syndrome type 2, please tell your study doctor because you should not receive LY3298176. If you are participating in a long-term study with LY3298176, your calcitonin, a hormone made by your thyroid, may be measured.

Additionally, it is possible that you could have other unknown side effects while taking LY3298176.

You should not take LY3298176 if you are pregnant or may become pregnant. Female rats that were given LY3298176 had irregular menstrual cycles and body weight loss or decreased body weight gain or both. Pregnant rats and rabbits that were given LY3298176 and lost too much body weight had offspring that were smaller than normal. Some of these offspring had malformations (organ development abnormalities). Because LY3298176 has only been tested in pregnant animals, humans who take LY3298176 while pregnant may experience other unknown side effects.

Procedure Risks

Blood Tests

For most people, needle punctures for blood draws do not cause any bad 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.

Eye Exam

You may receive drops in your eyes during your eye exam that will dilate your pupils (small openings in the middle of your eyes). Dilated pupils may make it difficult for you to drive, work in bright light, or read for a while after your appointment.

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.

Subcutaneous (SC) Injection

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.

Questionnaires

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

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

What are the Reproductive Risks?

Taking part in this study can result in risks to an unborn child 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, and can become pregnant, you must use 2 forms of birth control, where at least 1 form is highly effective for the duration of the study. You must continue to use birth control for 2 months after the last dose of the study drug. You should talk with your doctor about the types of birth control that are best for you and your partner

and that meet the study criteria, as some methods of birth control may be less effective. Tell your doctor right away if you become pregnant or think you are pregnant. The study doctor will want to follow your pregnancy and record its outcome.

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

If you are male, you should not father a baby while in this study. You must use a male condom with spermicide and discuss risk to the fetus with your partner(s) and request that your partner use appropriate contraceptive methods. You must continue to use the birth control for 4 months after the last dose of the study drug. You should talk with your study doctor about the types of birth control that are best for you and your partner and that meet the study criteria, as some methods of birth control may be less effective. Tell the study doctor right away if your partner becomes pregnant or thinks she may be pregnant. Also, you should not donate semen/sperm during the study or for 4 months after the last dose of study drug.

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

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

Please discuss birth control methods with your study doctor.

Other Risks

In addition to the side effects already described, tirzepatide (LY3298176), and the study procedures may have other unknown risks.

You could have a potential worsening of your obesity and/or T2DM if you receive placebo, a solution that looks like the study drug but has no medicine.

Depression is known to be more common in individuals with obesity or overweight and can be related to suicidal thoughts and behaviors. If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).

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.

You should read the entire instruction for use document before using the single-dose pen. If you do not follow the instructions, you may get too little study drug. If you use the pen incorrectly, you could break it or jam it and you may get too little study drug. If any part of the pen looks like it is damaged or broken, do not use the pen and return it to your study doctor or study staff.

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 T2DM may be helped.

Information obtained from this study will 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 condition. Other treatment options for obesity or overweight, including lifestyle modification, pharmacotherapy, and bariatric surgery are available.

The current standard of care for diabetes is diet and exercise with 1 or more medications. Your other choices may include:

- insulin or other glucose lowering drugs
- special diet or other lifestyle changes
- getting treatment or care for your diabetes without being in a study

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 LY3298176 or new information about LY3298176 safety or effectiveness.

If you stop being part of this study, the study doctor or one of the study staff members will talk to you about any medical issues regarding the stopping of your participation.

What are the costs of taking part in this study?

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

Greenphire Travel Reimbursement program is providing payment for inconvenience fees and travel reimbursement. 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 of $75 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following visits: V1, V7, V8.

You will be provided a fixed amount of $150 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following visits: V2.

You will be provided a fixed amount of $125 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following visits: V3, V9, V21, and if applicable the ET/ED visit.

You will be provided a fixed amount of $100 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following visits: V4, V5, V6, V12, V15, V18.

You will be provided a fixed amount of $25 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following telephone visits: V10, V11, V13, V14, V16, V17, V19, V20.

You will be provided a fixed amount of $25 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for V99, if applicable.

You will be provided a fixed amount of $50 per study visit for inconvenience fees related to time spent for lost wages and burden of the study for the following visits: v801 and if applicable, unscheduled visits conducted in accordance with the protocol.

The table below summarizes the fixed amounts you will be provided, per study visit for inconvenience fees.

Visit	Amount
V1, V7, V8	$75
V2	$150
V3, V9, V21, ED/ET (if applicable)	$125
V4, V5, V6, V12, V15, V18,	$100
TV10, TV11, TV13, TV14, TV16, TV17, TV19, TV20, V99 (if applicable)	$25
V801; unscheduled visits conducted in accordance with the study plan	$50

Abbreviations: V= Visit, TV= Telephone Visit, ET/ED= Early Discontinuation Visit

You will also be provided a fixed amount of $75 per study visit for caregiver inconvenience fees for visit 2.

The table below summarizes the fixed amounts your caregiver will be provided, per study visit for inconvenience fees.

Visit	Amount
V2	$75

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 up to $100. 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 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 visits 2-6, 9, 12, 15, 18, 21, and if applicable, Early Discontinuation Visit $25 per meal.

- If you travel greater than 90 miles round trip:
  - Additional meal reimbursement will be provided for visits 2-6, 9, 12, 15, 18, 21, and if applicable Early Discontinuation Visit up to $25 per meal.
  - Hotel stay reimbursement for you will be provided at visits 2-6, 9, 12, 15, 18, 21, and if applicable, Early Discontinuation Visit. 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.

You will get paid after each completed 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. 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 required for IRS reporting. >

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.

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 become ill or are injured while you are in the study, please seek medical help right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need

If you follow the directions of the study doctor and study staff, the sponsor will pay the medical expenses for the treatment of a physical injury because of a properly given drug or procedures. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participants, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00048731.

Authorization to Use and Disclose Protected Health Information

Will my medical information be kept private?

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

By signing and dating 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 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 (such as the U.S. Food and Drug Administration – [FDA] and in other countries, and
    - the ethical review board overseeing this study (such as Advarra IRB
- 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
    - the ethical review board 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 personal health information may no longer be protected under the Health Insurance Portability and Accountability Act (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. In California and any other state that requires an expiration date, this authorization will expire 50 years after you sign and date this document.

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 at the address listed on the first page of this form. If you cancel your authorization:

- The study doctor and study 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.

Statement of Authorization

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

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

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 and date 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, study nurses, or other study 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)	

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)