PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: A Prospective, Randomized, Double-masked, Sham-controlled, Multi-center, Two-arm, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal Tarcocimab Tedromer in Participants with Diabetic Retinopathy (DR) – GLOW2

PROTOCOL NO: KS301P108

STUDY DOCTOR: Eric K Chin, MD

STUDY SITE: Retina Consultants of Southern California
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TELEPHONE: 909-335-8940 (24 hours)

SPONSOR: Kodiak Sciences Inc.

You are invited to take part in a research study because you have been diagnosed with diabetic retinopathy (DR).

This form describes the study and your role as a possible participant. Please take your time to read this form with care and ask the study doctor or study staff all your questions. When you understand what is in this form, you will be asked to sign and date this form before you have any study procedures. You will receive a copy of the signed and dated form.

Your participation in this research study is voluntary, meaning that you can choose if you want to take part in the study. You can leave the study at any time, without any reason. Doing so will not change your health care or your rights. If you do not want to join the study, you can talk to the study doctor about your health care. Before you decide, it is important that you understand why the study is being done and what it will involve.

Kodiak Sciences Inc. (hereafter referred to as Kodiak) is the drug company that will manage and pay for this study. The study doctor is paid by Kodiak to conduct this study.

This is a study of an investigational drug called tarcocimab, which is being developed by Kodiak for the possible treatment of patients with retinal vascular disorders that cause vision loss or threaten vision, such as diabetic retinopathy.

An Institutional Review Board (IRB) has reviewed this study to make sure that your rights and welfare are protected after you join this study. This committee will watch over this study while you are in it.

INFORMATION ABOUT THIS STUDY

Why is this study being done?

Diabetic Retinopathy (DR) is a complication of diabetes that affects the eyes. It is caused when high blood sugar levels in the body damage the blood vessels of the light-sensitive tissue at the back of the eye (retina). All patients with diabetes mellitus are at risk of developing DR, a progressive condition that can result in severe vision loss. DR in its earliest stages is called “mild, non-proliferative” DR (NPDR) and mild damage can be seen in the blood vessels of the eye at this stage, but there may be no noticeable symptoms. Over time, the damage to blood vessels in the eye can worsen, and as this happens, the chances of vision loss from diabetes increase. The better you can overall control your diabetes, the lower the chances of developing vision loss over time.

As the severity of DR increases, there is a risk of developing complications that may result in vision loss or need treatment to prevent vision loss. These include:

- Proliferative Diabetic Retinopathy (PDR): growth of abnormal new blood vessels in the retina. The vessels may bleed, causing vision loss and scarring.

- Diabetic Macular Edema (DME): occurs when the macula, the area of the retina that enables clear, sharp vision, becomes swollen. This results in blurry vision.
- Anterior Segment Neovascularization (ASNV): growth of abnormal new blood vessels in parts of the front of the eye which can result in elevated pressure in the eye and vision loss.

To participate in this study, you must have diabetic retinopathy that has reached at least a moderately severe stage of NPDR, up to mild stage PDR. If you agree to participate in this study, photographs of your eyes will be taken to assess your diabetic retinopathy and determine if you meet these requirements.

A protein called VEGF (vascular endothelial growth factor) is present inside the eye at excessive levels in people with DR. Tarcocimab is a drug that blocks VEGF when injected into the eye. It is designed to last for a longer time inside the eye compared to other VEGF-blocking medicines.

The purpose of this study is to determine whether tarcocimab is safe and effective as a treatment for DR. In this study, tarcocimab will be given and changes in DR severity and the rate of development of sight-threatening complications will be compared between people who do or do not receive tarcocimab.

Tarcocimab has been tested in people and in animals and has been shown to be safe and well tolerated so far. Tarcocimab is an investigational drug, which means it is a drug that is being tested and has not yet been approved by the regulatory authorities, such as the U.S. Food and Drug Administration (FDA).

In this document, you may see the terms “treatment” and “treatment period”. These are terms used in research studies and these terms do not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this study drug.

This study will be conducted at approximately 50 study sites in the USA. Approximately 250 people (men and women) aged 18 and older are expected to take part in this study.

What will happen during the study?

In this study, the standard dose of tarcocimab will be compared to sham treatment. You will be randomly assigned (by chance, like the flip of a coin) to receive either tarcocimab or sham study treatment. Your chance of receiving tarcocimab is 50%, and your chance of receiving sham study treatment is 50%. Each group will have about 125 participants.

This study is double-masked, which means that neither you nor the masked study doctor or study staff will know what study treatment you are receiving. An exception to this is the unmasked study doctor who administers the study treatment; he or she is informed about your study treatment but will not share this information with you or the masked study team.

If you are assigned to the tarcocimab group, you will receive the tarcocimab study treatment given by injection into one of your eyes, the study eye, by an ophthalmologist (a medical doctor specializing in the treatment of eyes). If both of your eyes are affected, the more severely affected eye will be the study eye. Before the tarcocimab injection is given, eye drops or an injection will be used to numb your eye, and your eyelids and eye will be disinfected. You will receive 5 injections during the 1 year (48 weeks) of the study: the first at Day 1, then at Week 4, Week 8, Week 20 and Week 44.

If you are assigned to the sham group, you will receive 5 sham (pretend) injections in the 1 year (48 weeks) of the study: the first at Day 1, then at Week 4, Week 8, Week 20, and Week 44. Your eye will still be made numb and your eyelids and eye will be disinfected in preparation for an injection, but instead of an actual injection of study drug into your eye, a small amount of pressure will be applied to your eye using a blunt syringe, to pretend that you are receiving an injection. Because your eye will be numb, you will not know if you received an actual or sham injection.

During the study, if you develop a DR complication (DME, new or worsening PDR and/or ASNV), you will receive tarcocimab to treat it, regardless of the study group that you were assigned to at the beginning of the study (tarcocimab or sham). You will receive 2 injections, 4 weeks apart, followed by an injection every 12 weeks. You may receive additional tarcocimab injections more frequently based on your condition and the study doctor's opinion. Your study doctor may also recommend laser treatment which is used in addition to or instead of anti-VEGF injections as a treatment for the complications of PDR and/or ASNV in some situations.

There will be several screening examinations, tests, and procedures that you will undergo to find out if you are eligible for the study. If you are not familiar with any of these procedures, please ask your study doctor to explain how they are performed. If your screening results indicate that you are eligible to continue in this study, you will be asked to come back to the study site on Day 1 for study dosing. After Day 1, you will have another 6 study visits, for a total study duration of approximately 1 year. Each visit may take up to 2 hours. The last visit of the study is at Week 48.

The following assessments will be performed during the study:

- **Demographics and Medical History:** During the Screening Visit, the study doctor will ask questions about you, including your age and gender. You will be asked about your race and ethnicity (for clinical research purposes only). This is because we do not know whether the effects of the study drug are influenced by race or ethnicity. You will be asked about your medical history and, if you do not object, your study doctor may need to contact and obtain previous medical history or data from your other treating physician(s). This is done for your safety. A full eye history, including any prior eye treatments will be noted.
- **Vital Signs:** Your heart rate, blood pressure, and body temperature will be measured at Screening, Day 1, Week 20, and Week 48/Early Termination (ET) visits. Your height and weight will be measured at Screening only.
- **Pregnancy Test:** If you are a woman capable of becoming pregnant, you will need to provide a urine sample for the pregnancy test at Screening,

Day 1 and at each visit thereafter. If your urine test is positive, your blood will also be tested to confirm whether or not you are pregnant.

- **Blood Samples:** At Screening and Week 48/ET visits blood samples (about 2 teaspoons or 8 mL per visit) will be collected for routine safety laboratory tests, to check your blood cell counts, protein levels and to check your liver and kidney function.
- **Plasma Samples for Anti-Drug Antibodies (ADA):** At Day 1, Week 8, Week 32, and Week 48/ET visits, additional blood samples (about 1 teaspoon or 4 mL) will be taken to test for the detection of ADA. This is to understand potential immune responses that may also affect your response to tarcocimab.
- **Plasma Samples for Pharmacokinetic (PK) and Biomarker Testing:** At Day 1, Week 4, Week 8, Week 32, and Week 48/ET visits, additional blood samples (about 1 teaspoon or 4 mL) will be taken to test for PK (which measures how the study drug moves through the body) and biomarkers (a measurable indicator of the severity or presence of some disease state). At these visits, the concentration levels of tarcocimab in your blood will be tested to see how your body is processing the study drug. The levels of naturally occurring substances, or protein biomarkers, in your blood will also be measured to see if your response to tarcocimab is affected by these proteins in your blood.

  The total amount of blood that will be collected from you will be approximately 13 teaspoons or 52 mL over the entire duration of the study.

  Your blood samples will be sent for testing to Cenetron Diagnostics, LLC for safety testing, and to PPD Bioanalytical (Richmond, VA) or Kodiak Sciences Inc. (Palo Alto, CA) for ADA, PK and biomarker testing. Samples will be identified by a code and will not show who you are.

  ADA, PK and biomarker samples that are not immediately analyzed will be kept for a maximum of 5 years following the last participant's last visit of the study or the time that is required to complete the study, publish the data related to the study, and support any regulatory applications for the study drug, whichever is longer. Your blood samples will then be destroyed. You have a right to be informed of any plans for new analyses

on retained identifiable samples that are not currently foreseen, and you have the right to refuse further analyses.

Any remaining ADA, PK and/or biomarker samples not already used for testing in the study may be used for optional exploratory research. The research would be to evaluate VEGF levels in the blood and other blood factors such as systemic biomarkers to help researchers learn more about the disease. You are free to refuse to participate in this optional exploratory research for any reason, and this will not influence your participation in the study. Should you consent to participate in the optional exploratory research, you may withdraw your consent at any time during the storage period.

- **Best Corrected Visual Acuity:** is measured in both eyes at Screening, and Week 48/ET visits, and only in the study eye at all other visits. The sharpness of your vision will be measured by your ability to identify letters or numbers on an eye chart.
- **Eye Examinations:** are conducted in both eyes at Screening and Week 48/ET visits, and only in the study eye at all other visits.
  - Slit-lamp examination will include examination of your eyelids, the surface of your eye, and the inside of your eye including the pupils, iris, lens, and retina.
  - Eye pressure will be measured using a tonometer, a device that briefly touches the surface of your numbed eye to measure the pressure inside.
  - The retina will be examined more closely using an ophthalmoscope. For this test, you will be given eye drops to dilate the pupil to examine the back of your eye.

  After every injection (tarcocimab or sham injection), there will be a vision check and eye pressure will be measured for the study eye. You will be asked to stay in the clinic for approximately an hour after each injection to confirm that you are tolerating the injection well. If you are doing well after the injection, you may be able to leave sooner, or the study doctor may ask you to stay longer if further observation is needed after your injection.
- **Optical Coherence Tomography (OCT):** is measured in both eyes at Screening and Week 48/ET visits, and only in the study eye at all other

visits. OCT uses invisible light rays to take a picture of the back of your eyes and is done to measure the thickness of your retina.
- **Fundus Photography:** is conducted in both eyes at Screening and Week 48/ET visits, and only in the study eye at all other visits (except Day 1 visit, where it is not conducted at all). A special camera is used to take color photos of the back of your eye.
- **Fluorescein Angiography:** is conducted in both eyes at Screening. This test involves first injecting a dye into a vein in your arm and then taking photos of the back of your eye. These photos help to get a better look at the blood vessels and other structures in the back of the eye.

The frequency of your study visits and some of the assessments will change if you develop the DR complications of PDR, DME and/or ASNV.

What is expected from you?

When deciding whether to participate, consider whether you are able and willing to do the following:

- Keep your study appointments. If you cannot keep an appointment, contact your study doctor or study staff to reschedule as soon as you know that you will miss the appointment.
- Tell your study doctor or study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell your study doctor or research study staff if you experience pain or discomfort during any of the procedures required by this research study.
- While participating in this research study, you are not allowed to take certain treatments that may affect your study eye. You must alert your study doctor before taking any new medication during the research study. This is to protect you from possible harm that may result from combining medications.
- While participating in this research study, you should not take part in any other research study. This is to protect you from possible injury arising from such things as extra blood draws, the possible incompatibility between research drugs, and other similar hazards.
- Ask questions as you think of them.

- Tell your study doctor or research study staff if you change your mind about staying in the study.
- If you are female and you become pregnant, or if you are male and you get your partner pregnant, tell your study doctor as soon as you know (for additional information, please see section on “Are there any reproductive risks?” below).

What will happen at the end of the study or if you stop your participation early?

After the study drug is stopped, your study doctor will discuss your future options with you and may refer you back to your ophthalmologist or primary care doctor (if applicable).

If you have withdrawn from the study before its conclusion, your study doctor (or appointed delegate) may ask you to complete the Early Termination visit. If you fail to return for final assessments, one of the study site personnel may contact you by phone for a follow-up. This is done to have complete data about your health and safety at the end of the study. If you leave the study, there will be no penalty, and you will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care you are given.

The study doctor may stop the study drug or end your participation in this study for any of the following reasons:

- Staying on study drug or in the study would be harmful for you.
- If the study drug has caused any side effects to you.
- You need treatment that is not allowed in this study.
- You did not follow instructions about what to do in the study.
- The study is cancelled, or your study treatment group is stopped.
- If you are a woman of childbearing potential and become pregnant.

The study doctor will tell you the reason(s) why you should stop being in the study.

If you have experienced any side effects, you may be followed up until it is resolved. If not resolved, you may be followed up for 3 months. Your study doctor (or appointed delegate) may try to find out your long-term health status for a period of not more than 3 months by accessing your hospital records or publicly available sources such as national registries, newspaper obituaries, and social networking websites. Attempts may also be made to contact you or your relatives to collect this information. If you do not want this information about you to be collected, let your study doctor know at any time.

BENEFITS AND RISKS

Are there any possible benefits of being in the study?

Taking part in this study may or may not help to treat your Diabetic Retinopathy. If the study drug is effective, your diabetic retinopathy may improve in its severity, meaning that the risk of developing sight-threatening complications of DR could be lower for you. Additionally, if you already have or develop the sight-threatening complications of DR, being treated with tarcocimab may help improve your vision or reduce the severity of those complications. It is possible that you may not personally benefit from your participation in this study. However, by taking part, you will provide new information that may benefit other people in the future.

What are the potential risks and discomforts?

You may have side effects from the drugs or procedures used in this study. Side effects can vary from mild to very serious and may vary from person to person. Everyone taking part in the study will be watched carefully for any side effects.

Possible risks from receiving the study treatment, tarcocimab:

- Tarcocimab may not improve your diabetic retinopathy or your vision. The damage to the back of your eye due to your diabetes may get worse and/or your vision, if affected by DR, may get worse. Large studies of eye injections that block VEGF as a treatment for diabetic eye disease

complications have suggested approximately 5 to 10% of participants may be expected to lose 15 or more letters (3 lines on the visual acuity chart) over time, regardless of the specific intravitreal anti-VEGF agent used.

- Eye inflammation and cataract (clouding in the eye's lens) has occurred in the eyes of people after injections of tarcocimab. Whether tarcocimab has a higher, lower, or the same potential risk of eye inflammation or cataract as other eye injections that block VEGF is not known at this time.
- Some people taking other standard eye injections that block VEGF have had heart attack, stroke, or death. It is not known if the eye injections caused these problems. People with diabetes can have these problems more often because of their diabetes. Tell your study doctor if you have had a heart attack or stroke in the past. Whether tarcocimab has a higher, lower, or the same potential risk of heart attack or stroke as other eye injections that block VEGF is not known at this time.

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

- Severe eye inflammation, with eye pain, sensitivity to light, or redness
- Rash
- Fast pulse
- Sweating
- Feeling of dread
- Swelling around the eyes and mouth
- Swelling of the throat
- Wheezing
- Having a hard time breathing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Inability to breathe without assistance

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

The study drug might have other side effects, including serious ones, which are not known at this time. Such side effects cannot always be predicted.

If new information is discovered that might change your decision to stay in the study, you will be told about it and asked to sign and date an updated informed consent form (ICF).

Eye injections in general can cause other eye problems. Known very common side effects, or side effects observed in more than 10% of participants, include the following:

- Bleeding under the skin of the eye – the white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye and due to the eye injection procedure. It will not change how well you see and will usually clear up in about a week.
- Eye irritation and pain – your eye may feel irritated or painful and make a lot of tears for a few hours.
- Cataract (clouding of the eye's lens).
- Vitreous detachment (separation of the gel like substance in the middle of the eye from the retina – light-sensitive tissue at the back part of the eye).
- Increased eye pressure.
- Feeling that something is in your eye.
- Floaters (spots in your vision) – you might see small specks or floaters. Many people already have floaters. These new floaters may go away in a few days or you may stop noticing them.

Known common side effects, or side effects observed in less than 10% of participants receiving eye injections include the following:

- Eye inflammation – the inside of your eye can become irritated and inflamed due to the injection procedure or due to the study drug.
- Damage to the retina – the retina can become torn or detached due to the eye injection. If you see a curtain over your vision or part of your vision becomes missing, you should let your study doctor know right away.
- Damage to the cornea or other structures of the eye.
- Bleeding within the eye.

- An infection inside the eye. This happens rarely with any injection inside the eye but can be serious.

Some of these complications are rare, yet may lead to severe, permanent loss of vision.

Blood Tests

When a sample of your blood is taken, you may experience some temporary discomfort, bruising, swelling, and/or, in rare circumstances, infection at the needle site. You may feel dizzy or you may feel faint. There is also a small risk of nerve damage at the place where the needle is inserted, which can be permanent in rare cases.

Eye Examination

For the eye examination, your pupils will be dilated using eye drops. Dilation of the pupil may cause light sensitivity and slight blurring of vision for up to 4 hours after the examination. Wearing sunglasses for several hours after dilation can help reduce the discomfort of light sensitivity. Driving may be difficult, and it is better to have someone take you home. On the day of the visit, you should refrain from driving and operating machinery.

Fluorescein Angiogram

After the yellow dye (fluorescein) is injected into a vein in your arm or hand, your skin may turn yellow for several hours. The yellow color will disappear as your kidneys remove the dye from your body. Because the dye passes through your kidneys, your urine will turn dark orange for up to 24 hours after the procedure. You may have an upset stomach during the procedure, but this usually lasts only a few seconds. If the dye leaks out of your vein during the injection, some of the skin around the injection site may feel uncomfortable or become yellow. The discomfort usually lasts a few minutes, and the yellow color goes away in a few days.

Also, injection of the fluorescein dye may cause pain at the site of the injection and carry a risk of bleeding, bruising, and/or infection at the puncture site.

An allergic reaction to the fluorescein is rare. If this does happen, you may have a rash or experience itching of your skin. A severe allergic reaction occurs very rarely (fewer than 1 in 1 million people) and may involve breathing and/or heart rhythm problems, which can be life-threatening. The study doctor will monitor you closely after the dye is injected and you may need to stay at the clinic for a little while afterwards to check that you are okay.

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

Are there any reproductive risks?

Women:

It is not known if tarcocimab may affect an unborn child or nursing child. For this reason, if you are pregnant, breast-feeding or planning to become pregnant, you may not participate in this study. If you are capable of becoming pregnant, and are having sex with a man, you must use an acceptable method of birth control (see below) during the entire study and for 3 months after the last study drug injection. During the study, if you think that you might be pregnant, you should tell your study doctor right away, as your participation in the study must be stopped. Data and information about your pregnancy and delivery may be collected. Pregnancies occurring up to 3 months after the last dose of the study drug must also be reported to the study doctor. The study doctor may arrange for you to be counselled by a specialist, to discuss the risks of continuing with the pregnancy and the possible effects on the unborn child. Monitoring of your pregnancy will continue until the outcome is known.

Men:

It is not known if tarcocimab may affect your sperm or an unborn child. For this reason, you must use an acceptable method of birth control (see below) throughout the entire study. You should not donate sperm or father a child during the study or within 4 months following the last dose of study drug. It is important that you tell the study doctor immediately if your partner becomes pregnant during the study. Your partner may be asked to sign and date a separate consent form for the collection of data about the pregnancy and the outcome of the pregnancy, if required by country regulations.

Birth Control Methods for Men and Women:

Birth control methods with a failure rate of less than 1% per year are considered acceptable for this study and include the following:

- Bilateral tubal ligation
- Oral birth control (when properly used)
- Birth control patch
- Long-acting injectable birth control (hormonal implants)
- Vasectomy (male sterilization)
- Intrauterine device
- Sexual abstinence (if in accordance with your normal lifestyle)

Men must use a condom with their female partner, who are highly encouraged to use one of the birth control methods detailed above.

Birth control methods that have a failure rate of 1% or more are not acceptable and include a cap, diaphragm, or sponge with spermicide, or a male or female condom with or without spermicide. You must discuss with the study doctor the type of birth control method that you use, and the study doctor must approve that method before you can enter the study.

Are there any alternative treatments?

Your study doctor will explain the risks and benefits of other treatments before you decide if you want to take part in the study. If you decide not to

participate in this study, you may receive the standard treatment(s) for DR recommended by your doctors, which may include treatment of your underlying diabetes, eye injections, and/or laser treatments for your eye.

COSTS AND COMPENSATION FOR STUDY PARTICIPATION

Are there any costs if you decide to take part in the study?

The study drugs will be made available to you at no charge, and you will not be required to pay for any study procedures. You or your insurance company may be billed for any standard medical care that is not required for the research study.

Transportation may be provided to take you to and from your study visit(s) at no cost to you. If transportation is not available to you or you are unable to use it, you may be reimbursed for any reasonable travel expenses (bus/train/rideshare/taxi fares) incurred as a result of taking part in this study if you provide a receipt. Reimbursement of your travel expenses will be performed directly by your study site. Your study doctor will inform you about the options available to you.

You or your insurance company may be billed for any standard medical care that is not required for the research study.

Will you receive any payment if you take part in the study?

You will receive payment for participation in this study. You will receive $100.00 per completed in-office visit. If you do not complete the study, you will be compensated for the visits you do complete. A completed visit means all scheduled study procedures have been carried out.

You will be paid at each study visit.

If you have any questions regarding your compensation for participation, please contact the study staff.

Will you receive compensation for injury resulting from the study?

It is important that you take care to follow all the instructions given by the study doctor and study staff about this study. You should inform the study doctor as soon as you feel that you have had an illness or injury related to the study, so that you can get proper health care. If you are injured because of your participation in this study, you will be entitled to receive compensation according to the local law. Your study doctor will explain more about this to you.

Treatment for the injury will be made available through the study doctor and study site. You are not waiving any legal rights by signing and dating this form, accepting medical care, or accepting payment for medical expenses.

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.

WILL INFORMATION ABOUT THIS STUDY BE PUBLICLY AVAILABLE?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

This Web site only shows data in English, but you can request information from the study staff at any time and have access to data that are publicly available.

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

CONTACTS

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 questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

STATEMENT OF CONSENT

- I have read and understand the statements in this informed consent form.
- I have had the opportunity to ask questions, and I am satisfied with the answers given to me.
- I agree to take part in this study of my own free will.
- I understand that I will receive a copy of this signed and dated written informed consent form.

Kodiak would like you to allow them to use any remaining samples of your blood for optional exploratory research that may help understand more about NPDR.

☐ Yes, I agree for my blood samples to be used for exploratory research related to NPDR

☐ No, I do not agree for my blood samples to be used for exploratory research related to NPDR

Kodiak would like you to allow them to use your coded medical information for future medical or pharmaceutical research purposes.

☐ Yes, I agree for my coded medical information to be used for future research related to NPDR

☐ No, I do not agree for my coded medical information to be used for future research related to NPDR

Printed Name of Participant, in full

Signature of Participant **Date**

I have presented the study and answered the participant's questions.

I will give the participant a copy of this signed and dated informed consent form.

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

Signature of Person Obtaining Consent **Date**

Witness Signature for Participants Who Cannot Read

The participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

Printed Name of Witness (if applicable), in full

Signature of Witness **Date**

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE, SHARE AND DISCLOSE PERSONAL HEALTH DATA

STUDY TITLE: A Prospective, Randomized, Double-masked, Sham-controlled, Multi-center, Two-arm, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal Tarcocimab Tedromer in Participants with Diabetic Retinopathy (DR) – GLOW2

PROTOCOL NO: KS301P108

What will happen to your data?

This research study may be performed only by collecting and using your medical information.

Your study records will be kept as confidential as possible, except as necessary to conduct or support this study and as otherwise described in this document. For information shared beyond the study site, only a number will be used to identify you. You will not be personally identified in any reports or publications that may result from this research study. Because of the research goals of this study, however, your study records cannot be kept completely confidential.

The study staff, the Sponsor, and its agents will need to review the medical information collected from you for use in this study in order to accurately record information for this study. In addition, in order to review the study findings, the US Food and Drug Administration (FDA) and other regulatory agencies may review your medical records. The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing and dating this form, you are authorizing such access. If you do not sign and date this form to authorize access, you will not be able to participate in this research study.

The medical information that will be collected from you if you participate in the study includes the following:

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical history, vital signs, blood and urine tests, visual acuity, eye examinations, OCT, fundus photography, and fluorescein angiography.
- Information that is created or collected from you during your participation in the study, including the results of the tests included in the previous bullet point and any other procedures performed during the study.
- Information contained in your medical records that is related to your medical history and treatment.

The medical information collected may contain your name, address, telephone number, social security number, health plan number, study number, date of birth, dates of various medical procedures, and other personally identifying information.

If you sign and date this form and participate in the study, the study staff will be authorized to use the information described above for the purposes of the study. The study staff will also be authorized to provide access to or disclose the relevant information described above to the following parties involved in the study:

- Kodiak, the clinical research organization, or other agents designated by Kodiak to collect or review study data for verification of study procedures and/or side effect reporting
- Other employees or students of Kodiak or its authorized agents, who may accompany study monitors and auditors for quality and training purposes
- The institutional review board (IRB) that oversees the research study at your study site
- Government regulatory agencies, including the FDA
- Other parties and officials, as required by law, court order, or other legal mandate

Once your information is disclosed to the Sponsor, its agents, the IRB, or government agencies as described above, it is possible that your medical information will be re-disclosed. In addition to disclosures to the entities identified above, your coded health information may also be disclosed to others involved in the research study, such as the following:

- Laboratories or offsite testing facilities for clinical tests required by study plans
- Approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements
- Kodiak who directs the medical research studies
- Other third parties contracted by Kodiak to provide services related to studies

The study data may be transferred to other countries for processing, including countries that are not covered by data protection legislation.

While the study is in progress, your access to your study records may be limited. In order to protect the scientific integrity of the study, the treatment you receive in this study needs to remain unknown (for example, masked) until the study data are analyzed.

You may have the right to see and copy the medical information collected from you for the study for as long as that information is maintained by the study staff and other entities.

Study data, including your coded medical information, may be used and shared for pharmaceutical research purposes related to this study. This authorization has no expiration date, except for sites located in CA, MN, IL, where the authorization expires 50 years from the date signed. In signing and dating this form, you authorize the use and disclosure of your information for purposes of the study and for future research purposes at any time.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on the first page of this form. If you withdraw your authorization, data collected prior to your withdrawal may still be processed and stored along with other data collected as part of the study. Normally, no new information will be collected for the study database unless you specifically consent to it. However, the law does require that any side effects that you experience are documented and reported. To complete the study findings, your long-term health status may also be obtained from public sources.

The Sponsor has contracted vendors, which will know your real identity, although they will only be informed about your medical condition, if necessary, to perform the service being provided.

To ensure your privacy, your name and other directly identifying information will not be attached to records or samples released for research purposes.

Only the study doctor and authorized personnel will be able to connect this code to your name. Your coded data will be forwarded to Kodiak and its service providers for activities related to the study (for example, laboratory analysis).

The data will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported or published. If the results of the study are published, your identity will remain confidential.

Under federal data protection law, the **Health Insurance Portability and Accountability Act (HIPAA), and specific regional regulations,** your study site shall be responsible for ensuring that your information is safeguarded. You have the right to access, through your study doctor, all the information collected about you and, if applicable, to ask for corrections. However, in order to protect the scientific integrity of the study, the treatment you received in this study needs to remain unknown (for example, masked) until the study data are analyzed, unless otherwise required be made known (for example, unmasked) by law or regulation. Recipients of your information may be in countries that do not have data protection safeguards and rights. Kodiak, its authorized representatives, and regulatory authorities shall, in all cases, seek to maintain confidentiality within the limits of local laws.

If you should withdraw from the study, data collected prior to your withdrawal may still be processed along with other data collected as part of the study. Normally, no new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side effects that you experience are documented and reported. You have the right to require that any previously retained samples are destroyed.

What if you change your mind and do not want your data to be used or disclosed?

If you leave the study early, data obtained while you were in the study may still be kept with other data obtained as part of the study. Normally, no new data will be obtained for the study unless you clearly agree to that. However, the law requires that you report side effects that you experience even after you leave the study.

AUTHORIZATION

- I understand that I will receive a copy of this signed and dated written authorization form as well as a copy of the Experimental Subject's Bill of Rights.
- I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form.

Printed Name of Participant, in full

Signature of Participant **Date**

Witness Signature for Participants Who Cannot Read

The participant has indicated that he/she is unable to read. The authorization document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

Printed Name of Witness (if applicable), in full

Signature of Witness **Date**