

Version 4.1.2 Dated 08Feb2024  
(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)  
USA Main Informed Consent Form  
Participant Information and Informed Consent Form

GS-US-457-6411

## **UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Sponsor / Study Title:** **Gilead Sciences, Inc. / “A Phase 2, Double-Blinded, Randomized, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of GS-5290 in Participants with Moderately to Severely Active Ulcerative Colitis”**

**Protocol Number:** **GS-US-457-6411**

**Principal Investigator (Study Doctor):** **Kendall Beck, MD; Assistant Clinical Professor Division of Gastroenterology Department of Medicine UCSF Center for Colitis and Crohn’s Disease 1701 Divisadero Street, Suite 120 San Francisco, CA 94115 Phone: 415-502-4444 (24 Hours)**

**Study Coordinator:** **Maddie Broyles  
Phone: 415-353-7383  
Email: Maddie.broyles@ucsf.edu**

This is a clinical research study. Your study doctor, Kendall Beck, MD, or her study team from the Gastroenterology Faculty Practice at UCSF will explain this study to you.

### **WHAT IS A CLINICAL RESEARCH STUDY?**

You have been asked to take part in a clinical research study. This study will test an experimental drug named GS-5290 for the treatment of Ulcerative Colitis (UC).

An experimental drug is one that is currently being tested. It has not been approved by the Food and Drug Administration (FDA) for sale in the United States or by any regulatory authorities in any country in the world.

A clinical research study is part of healthcare science that determines the safety and effectiveness (efficacy) of medications intended for human use.

This Participant Information and Informed Consent Form explains the study. Your study doctor or study staff will go over this form with you. Your study doctor or study staff will answer all questions you have about the information in this form. You should understand the purpose of the study, how taking part may or may not help you, any potential risks it may cause to you, and what is expected of you during the study.

If you agree to take part, you will be asked to sign and date this form. Your study doctor or study

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

staff will sign and date this form and you will be given a signed and dated copy to keep for your records. No one can force you to take part in this study.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

You have been asked to participate in this study because you have been diagnosed with UC, which is a chronic inflammatory disease of the large intestine.

The purpose of this study is to see if GS-5290 is effective and safe in treating people with moderate to severe UC.

The study will compare people in different study treatment groups who receive GS-5290 with people who receive placebo. People who receive placebo will take a tablet that looks like GS-5290, however, the tablet will not contain any active drug.

### **HOW DOES THIS STUDY WORK?**

If you agree to take part in this study, you will be one of approximately 176 participants in this study. The study will take place at approximately 125 study sites located in approximately 15 countries globally. Your study doctor has asked you to come to the clinic for a screening visit to see if you are able to take part. Entry into screening does not guarantee enrollment into the study. In order to manage study enrollment, Gilead (the study sponsor), at its sole discretion, may stop screening and/or enrollment at any site or the whole study at any time.

This is a randomized, double-blind, placebo-controlled, dose-ranging study.

Randomized means the study treatment you take will be chosen by chance - like flipping a coin. You will be assigned to a study treatment program by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Double-blind means you and your study doctor or study staff will not know what study drug or dose you will be taking.

Placebo-controlled means that you may be taking a tablet with no medicine in it but looks like tablets containing GS-5290.

Dose-ranging means that different amounts of GS-5290 are being tested to establish which dose works best.

The main study will consist of 2 phases: a Blinded Study Treatment Phase and a Non-responder (NR) Study Treatment Phase.

#### **Blinded Study Treatment Phase:**

- Day 1 to Week 12: Active or placebo-to-match Study treatment

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

If you agree to take part in this study and meet all of the entry requirements, you will be randomized, and you will have 1 out of 4 chances to receive GS-5290 (600 mg), 1 out of 4 chances to receive GS-5290 (300 mg), 1 out of 4 chances to receive GS-5290 (150mg) and 1 out of 4 chances to receive placebo for the first 12 weeks of the study.

At your Week 12 visit in the blinded study treatment phase, your study doctor or study staff will perform assessments, including blood tests and an endoscopy, to see how your body has responded to the study treatment. Your study doctor will use these assessments to determine whether your UC has improved, called clinical response. If you achieve clinical response at Week 12, you will continue in the blinded study treatment phase and receive either 300 mg or 150 mg GS-5290 depending on your prior assignment.

If there is not enough data to assess your clinical response (endoscopy and questions you answer daily on an electronic diary called an eDiary [a diary kept in an electronic format that your study doctor or study staff will provide and review with you]) at Week 12, you will discontinue the study and will not be eligible for the NR study treatment phase. You will complete the Week 12 visit followed by the post study treatment (PTx) visit 30 days after the last study dose.

If you do not achieve clinical response at Week 12 in the blinded study treatment phase and if you agree to take part in the NR study treatment phase, you will receive 12 weeks of GS-5290 study treatment and receive either 300 mg or 600 mg GS-5290 daily, depending on your prior assignment.

### **Non-Responder (NR) Study Treatment Phase:**

- Day 1 to Week 12: Active study drug, dosing amount may vary
- Week 12 to Week 52: Active 300 mg once daily

For the first 12 weeks in this phase, you and your study doctor will know that you are taking a tablet with GS-5290 but will not know how much of GS-5290 you are taking.

At your Week 12 visit of the NR study treatment phase, your study doctor or study staff will perform clinical response assessments again. If you achieve a clinical response, you will receive up to an additional 40 weeks of GS-5290 300 mg once daily. If you do not achieve clinical response or do not have enough data to assess a clinical response (endoscopy and questions you answer on a daily on an eDiary), you will discontinue study drug. You will complete the Week 12 visit followed by the post study treatment (PTx) visit 30 days after the last study dose.

At some point during the study, the study may be unblinded to you and your study doctor. Unblinded means that you and your study doctor will be told which study treatment you are receiving. If the study is unblinded to you and your study doctor, you will continue to receive the same dose of GS-5290 that was assigned to you while the study was blinded.

GS-5290 and placebo will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

### **HOW LONG WILL YOU BE ON THE STUDY?**

Taking part in the blinded study treatment phase of this study will last at least 12 weeks and up to 52 weeks, not including the screening visit.

The NR study treatment phase of this study will last at least 12 weeks and up to 52 weeks, after your participation in the blinded study treatment phase. The total duration of the study may be a maximum of 64 weeks.

During this time, you may be required to visit the clinic at least 17 times in the blinded study treatment phase and at least 15 times in the NR study treatment phase.

### **WHAT ARE YOUR RESPONSIBILITIES?**

If you decide to take part in this study, there are some rules you must follow. Some of the rules are highlighted in the list below. There could be other rules that your study doctor will review with you as this is not a comprehensive list.

- You must not get pregnant or get someone pregnant during the study and for 7 days after the last dose of the study drug.
- Female participants must not breastfeed during this study.
- It is very important that you tell your study doctor all the information you know about your health and medications you are taking now or start taking while in the study. If you do not tell the study doctor everything you know, you may be putting your health at risk.
- You are not allowed to take certain medications and herbal/natural supplements while in this study. Your study doctor will review your current medications and herbal/natural supplements with you to determine if they are allowed to be taken while participating in this study. You must consult with the study doctor before starting any new medications or herbal/natural supplements while participating in this study.
- You are not allowed to participate in another clinical research study with another study treatment.
- Male participants must not donate sperm until at least 7 days after your last dose of study drug.
- Female participants must not donate or harvest eggs until at least 7 days after your last dose of study drug.
- You should take the study drug exactly as instructed at approximately the same time every day and avoid missing any doses.
- You must bring back all unused study drug and all study drug containers (even if they are empty or used).
- You will need to complete an electronic diary (eDiary) on a daily basis and bring back the eDiary at each visit.
- You must agree to fast (no food or drink, except water), for approximately 8 hours before specific laboratory assessments as instructed by your study doctor.
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

- Some insurance companies require people who are renewing a policy or getting a new policy to tell them about participating in a clinical study. You should check with your insurer to determine if taking part in this study will affect your existing insurance policy.

### **WHAT WILL HAPPEN AT EACH STUDY VISIT?**

The table below shows what will happen each time you visit the UCSF Center for Colitis and Crohn's Disease at 1701 Divisadero Street, Suite 120, San Francisco, CA 94115. The procedures or tests are described after the table.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

**Study Procedures Table – Blinded Study Treatment Phase: Screening to Follow-Up**

Period	Screening		Blinded Study Treatment														Follow-up	
Week Procedure	(1 month)	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	ET	PTx
Informed consent	X																	
Review of your medical history	X																	
Physical exam and vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review your health and the medications you are taking	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Randomization		X																
Colonoscopy/Flexible sigmoidoscopy with biopsies	X					X										X		
12-lead ECG	X					X					X					X	X	
Answer questions about your UC and wellbeing	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Get study drug		X		X	X	X	X	X	X	X	X	X	X	X	X			
Stool sample	X					X										X		
Urine sample	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test for WOCBP	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood samples for study tests and health monitoring	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood samples for viral infections screening	X																	
Blood sample for biomarkers		X	X	X		X				X						X		
TB screening: blood sample. May include chest X-ray	X																	

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Period	Screening		Blinded Study Treatment														Follow-up	
Week Procedure	(1 month)	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	ET	PTx
Blood sample for UC genetic markers	X																	
Blood sample for measuring study drug levels			X	X	X	X			X							X		
Approximate total volume of blood taken at this visit	26.5 mL (about 5 teaspoons)	15.5 mL (about 3 teaspoons)	20.5 mL (about 4 teaspoons)	25.5 mL (about 5 teaspoons)	9.5 mL (about 2 teaspoons)	25.5 mL (about 5 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	9.5 mL (about 2 teaspoons)	15.5 mL (about 3 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	20.5 mL (about 4 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)

ECG = electrocardiogram; ET = early termination; PTx = posttreatment; TB = tuberculosis; UC = ulcerative colitis; WOCBP = woman of childbearing potential

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

**Study Procedures Table – Non-Responder Study Treatment Phase: Week 2 to Follow Up**

Period	Non-responder Study Treatment														Follow-up	
Week Procedure	2	4	8	12	16	20	24	28	32	36	40	44	48	52	ET	PTx
Physical exam and vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review your health and the medications you are taking	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Colonoscopy/Flexible sigmoidoscopy with biopsies				X										X		
12-lead ECG				X					X					X	X	
Answer questions about your UC and wellbeing	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Get study drug		X	X	X	X	X	X	X	X	X	X	X	X			
Stool sample				X										X		
Urine sample	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test for WOCBP	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood samples for study tests and health monitoring	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood sample for biomarkers	X	X		X				X						X		
Blood sample for measuring study drug levels	X	X	X	X			X							X		
Approximate total volume of blood taken at this visit	20.5 mL (about 4 teaspoons)	25.5 mL (about 5 teaspoons)	9.5 mL (about 2 teaspoons)	25.5 mL (about 5 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	9.5 mL (about 2 teaspoons)	15.5 mL (about 3 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)	20.5 mL (about 4 teaspoons)	4.5 mL (about 1 teaspoon)	4.5 mL (about 1 teaspoon)

ECG = electrocardiogram; ET = early termination; PTx = post study treatment; UC = ulcerative colitis; WOCBP = woman of childbearing potential



Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Procedure or Test	Description
Review your health history	Collect information about your health and past medical treatments, including but not limited to use of alcohol and drug use.
Physical exam	A complete physical examination will be performed at Screening, Week 12 and Week 52. Vital signs (blood pressure, heart rate, breathing rate, temperature), and body weight will be measured. Height will be measured at screening only.  Your study doctor may also perform a physical examination at any time during the study to determine if there has been any change in your health.
Symptom driven physical exam	This type of physical exam will be performed based on the signs and symptoms reported by you during the study. Your vital signs (blood pressure, heart rate, breathing rate and temperature) and body weight will be measured.
Colonoscopy or flexible sigmoidoscopy with biopsies	An outpatient procedure(s) where the inside of your large intestine (colon) and rectum are visually examined with a camera. The colonoscopy is more extensive than a flexible sigmoidoscopy and your study doctor will determine which test is needed and whether you will need medicines to relax you for the test. During the procedure, a small amount of tissue will be removed from the intestine and examined under a microscope to determine whether disease is present. Your study doctor will provide you with further instructions, including how to prepare for this procedure. This may be a separate visit from the visits described in this consent form. This procedure will take about 30 to 60 minutes.
Electrocardiogram (ECG)	Several small, sticky pads will be placed on your chest, arms, and legs. A wire from each pad goes to a machine that makes a recording of your heart rhythm. This test takes about 15 minutes.
Health related quality of life questionnaires	You will be asked to answer some questions about your health from your point of view on an electronic device.
Chest X-ray for tuberculosis (TB) assessment	A chest X-ray is a test that produces images of the structures inside your body using a small amount of radiation – particularly your lungs. This test takes less than 15 minutes. If you had a chest X-ray within the last 4 months and the results are available

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

	to the site, an X-ray of your chest may not be needed.
Tuberculosis (TB) assessment	At screening only, a blood sample will be obtained and tested to find out whether you have TB (an infection that can damage your lungs) or have had TB in the past. If you were previously treated for inactive TB, no blood test will be done, but an X-ray of your chest may be needed. Let your study doctor know if you have ever had TB or have been near another person who had TB. The study doctor may be required by law to report the result of these tests to the local health authority.

Study Drug	Description
Get study drug	At the visits marked on the table, you will be given study drug to take home with you. You will receive your first dose of study drug at your Day 1 visit. Store your study drug, GS-5290 tablets or matching placebo tablets, at controlled room temperature of 25°C (77°F).
Take study drug	Take your study drug 1 time per day on an empty stomach approximately the same time each day. You may consume food up to 4 hours before or at least 2 hours after you take your study drug. Tablets should be swallowed whole with water. If you miss a dose, do not take 2 doses to make up for your missed dose. On the days you have study visits that require certain blood samples, your study doctor or study staff will remind you not to take the study drug before your visit. Your study doctor will instruct you on when to take the study drug.
Bring back study drug and containers	At all study visits, bring back all unused study drug and all study drug containers (even if they are empty or used). Your study doctor or study staff will count how many doses you have taken. Your study doctor or study staff will ask about any doses you did not take or if you took any extra doses.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Lab Tests and Biologic Sample Collection	Description
Main Study Testing	
Study tests	Samples of your blood, urine, tissue, and stool will be used to help answer the study questions.
Routine health tests	Samples of your blood and urine will be tested to check your health.
Pregnancy tests	If you are a woman who can get pregnant, a sample of your blood will be taken to test for pregnancy at the screening visit. Urine pregnancy tests will be performed at study visits every 4 weeks after you enter the study. To take part in this study, the pregnancy test must be negative each time the test is taken.
Viral infection tests: Hepatitis B (HBV), Hepatitis C (HCV), Human immunodeficiency virus (HIV)	Samples will be collected to see if virus is in your blood at the screening visit. The study doctor may be required by law to report the result of these tests to the local health authority. Those who test positive for HBV at screening will require additional testing on this study.
Pharmacokinetic test (PK)	Samples of your blood will be tested to see how much study drug is in your blood. The blood sample will be collected before you take your study drug at Weeks 4 and 12 and after you take your study drug at Weeks 2, 4, 8, 12, 24, and 52.
Biomarker tests	Your blood, tissue, and stool will be collected for biomarker testing. Biological markers (biomarkers) are substances in the body that can offer clues as to how the drug is affecting the body and a disease. These tests will help answer study questions on whether the study drug is changing certain biological substances that are associated with the way the study drug is expected to work.
Urine drug screen	Sample of your urine will be tested for amphetamines, cocaine, barbiturates, opiates, and benzodiazepines.
Screening genomic sample	Genomics is the study of genes and their function (factors inherited from our parents and how they work). One sample will be collected to test your potential reaction to study drug.

**WHAT TESTS WILL BE DONE ON THESE MAIN STUDY STORED SAMPLES?**

Some of your blood, stool, and tissue samples taken during the study will be stored. Your stored samples and the information collected about you during the study may be used by the Study

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Sponsor, and its research partners or companies, to help answer main study questions. At the end of this study, your samples may be held in storage by Gilead for up to 15 years. If you decide to withdraw from the study, the study staff will not collect additional samples from you, although the Study Sponsor will retain and use any results already collected and may need to retain and use any samples that have already been collected. After concluding your study participation, you may request that your stored samples be destroyed by writing to the study doctor at the address listed in this form. Your specimens and/or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

**Blinded Results**

Some information provided from tests done on your samples will not be given to you or your study doctor. This information will not be placed in your medical records and will have no effect on your medical care.

**WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?**

Your study drug must be taken on an empty stomach (no food or liquids except water) up to 4 hours before or at least 2 hours after you take your study drug, GS-5290. At the Day 1 Visit, Weeks 4, 12, 28, and 52 visits, fasting (no food or liquids except water) is required. You may not eat or drink (except water) for 8 hours prior to each of those visits.

Your study doctor or study staff will remind you of these restrictions prior to your visit when these assessments are to be performed.

**WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?****GS-5290 COMMON SIDE EFFECTS**

GS-5290 is an experimental drug that is currently not approved for the treatment of any medical condition. GS-5290 is being tested for the treatment of inflammatory bowel disease. There are potential risks involved with taking GS-5290 and there is limited data available in humans at this time.

GS-5290 has been given to healthy participants in two phase 1 studies. In the first-in-human study, 54 volunteers were given GS-5290 for a short period (1 dose or 10 days of dosing) to study the safety of GS-5290. Few unwanted effects, called adverse events, were reported and all were mild in severity and didn't last long. Adverse events that occurred in more than one person during 10 days of GS-5290 dosing included: dizziness, nausea, or altered sense of taste. The most common laboratory abnormalities were mild to moderate elevations in two substances that are present in the blood called creatinine and bilirubin, but the affected participants had no related symptoms. The levels of creatinine and bilirubin returned to baseline after GS-5290 was stopped.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

Bilirubin is a normal waste product of aging red blood cells. GS-5290 may cause an increase of blood bilirubin levels, which may cause a yellow tint to your eyes or skin. During the study, a dedicated doctor will monitor the blood bilirubin levels and your study doctor will check for signs and symptoms of increased bilirubin levels.

Creatinine is a muscle waste product and blood levels are used to measure how well the kidneys are working. GS-5290 can interfere with the accuracy of the creatinine blood test by leading to increased levels of creatinine in the blood even though your kidney function is normal. During the study, an alternative laboratory test will accurately measure how well your kidneys are working.

In the other phase 1 study, GS-5290 was tested in 70 healthy volunteers in combination with other drugs to see how the different drugs interacted with GS-5290. No safety concerns were observed. If you are taking certain other drugs, your study doctor may adjust their dose or exclude you from the study.

In animal studies, GS-5290 was given to monkeys for 9 months and to rats for 6 months at very high doses. Immune cells in the small intestine of some of the animals reacted to the high levels of GS-5290, but the normal function of absorption of the intestines was not affected. Importantly, the dose of GS-5290 given to monkeys and rats was 3 and 16 times higher, respectively, than the dose of GS-5290 that will be used to study participants with UC; however, GS-5290 has only been studied in humans for short periods of time (10 days).

Your study doctor and the study sponsor will be monitoring you for signs of drug toxicity throughout the study. It is important that you inform your study doctor of any changes in your symptoms or appearance of new symptoms.

Inflammatory bowel disease involves an overactive immune system. The immune system also helps your body to fight infections. It is possible that using GS-5290 to treat your inflammatory bowel disease may lower your ability to fight infections. You will be monitored for signs and symptoms of infection during the study.

Please talk to your study doctor for more details on possible side effects of GS-5290.

## **BLOOD DRAWS**

Collecting a blood sample from a vein may cause pain, bruising, lightheadedness, fainting, and very rarely, infection at the site of the needle stick.

## **Electrocardiogram (ECG)**

After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches are attached. You may need to have your chest shaved for this procedure.

Version 4.1.2 Dated 08Feb2024  
(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)  
USA Main Informed Consent Form  
Participant Information and Informed Consent Form

GS-US-457-6411

## **COLONOSCOPY / FLEXIBLE SIGMOIDOSCOPY WITH BIOPSY**

Colonoscopy and flexible sigmoidoscopy are generally safe procedures but as with any procedures there are risks. These risks will be discussed with you by your study doctor.

Preparation for this test may require use of an enema or laxative, or both, which may cause abdominal discomfort and increased loose stools during the preparation period. Preparation may also include a special drink which empties your intestines of stool. You may experience cramping, temporarily, from the instrument used to inflate your colon during the procedure. Puncture of the colon is a rare side effect from this procedure. If you experience fever, chills, severe abdominal pain or heavy rectal bleeding, call your study doctor immediately.

## **QUESTIONNAIRES**

Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while answering these questions, please talk with your study doctor.

## **FASTING (Prior to certain study visits)**

Fasting could cause dizziness, headache, stomach discomfort, and/or fainting.

## **CHEST X-RAY**

You may receive some radiation exposure from a chest X-ray if this procedure is necessary. Generally, the amount of radiation received during this procedure is the same as a person gets from exposure to natural sources of radiation in the environment in a 10-day period. There is no evidence this additional radiation changes health risk. If you have any questions about the radiation used in this study, or the risks involved, please consult the study doctor conducting the study.

## **ALLERGIC REACTION**

Allergic reaction is always possible with a drug you have not taken before. Serious allergic reactions that can be life-threatening may occur. Some things that may happen during an allergic reaction to any type of medication include the following:

- Rash
- Having a hard time breathing
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast heart beat
- Sweating

As part of this research, your study doctor may be required to use one or more of the following: a web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

### **UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS**

There are side effects that are not known or happen rarely when participants take study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study.

As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed in this form.

### **PREGNANCY, BREASTFEEDING, AND CONTRACEPTION REQUIREMENTS**

The effects of GS-5290 on an unborn baby or a nursing infant are not known. For this reason, pregnant women, women who wish to become pregnant, and breastfeeding women will not be enrolled in this study. Women who are breastfeeding must stop nursing before their first dose of GS-5290.

If you or your partner becomes or suspects that you or your partner become pregnant while you are taking GS-5290 or within 30 days after the last dose of study drug, you must stop taking the study drug and notify your study doctor immediately. Because the risk to you and your baby is unknown, it is recommended that you/your partner seek medical supervision during you/your partner's pregnancy and for the baby after it is born. The Study Sponsor and you/ your partner's study doctor will not be responsible for the costs related to your pregnancy, delivery, or care of your child.

The Study Sponsor will collect information about your pregnancy and the outcome of your pregnancy.

If your partner becomes pregnant while you are taking study drug, they will be asked to sign a separate informed consent form to collect additional information about their pregnancy and the outcome of their pregnancy.

Version 4.1.2 Dated 08Feb2024  
(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)  
USA Main Informed Consent Form  
Participant Information and Informed Consent Form

GS-US-457-6411

**For Female Participants:**

You must agree to one of the following from screening until 7 days following the last dose of the study drug, GS-5290.

If you are able to become pregnant you must either completely abstain from sexual intercourse with a person of the opposite sex, OR consistently and correctly use one of the following highly effective methods of birth control:

- Nonhormonal or hormonal intrauterine device (IUD)
- Progestin only subdermal contraceptive implant
- Bilateral tubal occlusion or bilateral tubal ligation (upon medical assessment of surgical success)
- Vasectomy in the partner assigned male at birth (upon medical assessment of surgical success)

OR

If you wish to use a hormonally based method, you must use it along with a barrier method, preferably a male condom. Hormonally based contraceptives and barrier methods permitted for use in this protocol are as follows:

- Oral contraceptives (either combined or progesterone only). For oral combined hormonal contraceptives, the dosage of ethinyl estradiol present in the pill should not exceed 20 mcg
- Injectable progesterone
- Contraceptive vaginal ring delivering no more than 0.020 mg of ethinyl estradiol per day permitted
- Barrier methods (each method must be used with a hormonal method)
- Male condom (with or without spermicide)
- Female condom (with or without spermicide)
- Diaphragm with spermicide
- Cervical cap with spermicide
- Sponge with spermicide

If you are a female who is sexually active and able to become pregnant, please speak with your study doctor to determine the best method of birth control for you during this study. Not all of the methods may be approved and/or available in your country, please check with your study doctor.

You must also agree not to donate your eggs or to have in vitro fertilization while taking study drug GS-5290 and until at least 7 days after the last dose of study drug GS-5290.



Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

In the event of a delayed menstrual period (over 1 month between periods), a pregnancy test must be done to rule out pregnancy. This is applicable also for women who can get pregnant with infrequent or irregular periods.

### **For Male Participants:**

During the study, male participants with female partners who can get pregnant should use condoms when engaging in intercourse of reproductive potential, while taking study drug GS-5290 and until at least 7 days after the last dose of study drug GS-5290.

Male participants must agree to avoid sperm donation until 7 days after the end of the entire study. If your female sex partner becomes pregnant or suspects that she has become pregnant while you are taking GS-5290, you must notify your study doctor immediately. Because the risk to your pregnant partner and your baby is unknown, it is recommended that your partner seek medical supervision during your partner's pregnancy and for the baby after it is born. The Study Sponsor and your partner's study doctor will not be responsible for the costs related to the pregnancy, delivery, or care of your child.

If your partner becomes pregnant while you are taking study drug, they will be asked to sign a separate informed consent form to collect additional information about their pregnancy and the outcome of their pregnancy.

### **WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

Your taking part in this study may help people with UC understand more about the treatment of your disease. By taking part in this study, your health will be monitored closely at study visits.

You may not receive benefit from taking part in this study. Studies are a way for doctors to see if a drug is useful in treating a disease.

### **WHAT ARE YOUR TREATMENT OPTIONS?**

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

You can discuss if you want to have any treatment or if you want to choose another such as another anti-inflammatory medication or surgery to treat your disease. These treatments include those that are already approved and sold.

### **WHAT HAPPENS IF YOU DO NOT OR NO LONGER WANT TO TAKE PART IN THIS STUDY?**

Your decision to take part in this study is voluntary. You can refuse to take part or stop taking part at any time without giving a reason. If you decide to stop taking part in the study at any time, your exit from this study will not affect medical care which you otherwise may receive.

Version 4.1.2 Dated 08Feb2024  
(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)  
USA Main Informed Consent Form  
Participant Information and Informed Consent Form

GS-US-457-6411

Your participation in this study may be stopped at any time by your study doctor, the Study Sponsor, or health authorities.

Your study doctor may decide for your medical safety to stop your study drug or take you off the study. You may be taken off the study if your study doctor learns you did not give a correct medical history or did not follow instructions for the study. If you are taken off the study, you will no longer receive the study drug. If your study drug is stopped, your study doctor will closely monitor your overall health.

If you discontinue study drug early, you will be asked to return for an Early Termination (ET) visit followed by a Post Study Treatment (PTx) visit 30 days after last dose of study drug and return all unused study drug (including empty study drug bottles) as well as your eDiary.

### **HOW MUCH WILL STUDY TREATMENT COST YOU?**

The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

You or your usual health care payer will be responsible for any other health care costs.

### **WILL YOU BE PAID TO BE PART OF THIS STUDY?**

You will not be paid to take part in this study. You may be reimbursed for reasonable expenses (parking, travel, etc.) related to your study visits. This money is meant to help pay for things like travel costs, childcare costs, and missed hours from work. You will need to provide receipts or other documents to your study doctor or study staff in order to receive this reimbursement. This reimbursement may not exceed \$600 per calendar year. You will be reimbursed approximately 1 month after you submit your travel receipts to the study staff.

If you do not complete the study, for any reason, you will be reimbursed a prorated (partial) payment for each study visit you do complete.

You or your usual health care payer will be responsible for any other health care costs.

### **WHAT HAPPENS IF YOU ARE INJURED?**

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call the telephone number listed on the first page of the consent form.

Treatment and Compensation for Injury: If you are injured as a result of study drug or following study procedure, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, Gilead Sciences, Inc., depending on

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

a number of factors. The University and the study sponsor normally do not provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

If you receive Medicare benefits, the Sponsor, Gilead Sciences, Inc., is required by law to report payments made to you for treatment, complications, and injuries that arise from this study. Information that you are taking part in the study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

You do not give up any legal rights by signing this form. You are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

### **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 such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

**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 participant, contact:

By **mail**:

Study Subject Adviser  
Advarra IRB  
6100 Merriweather Dr., Suite 600  
Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: [adviser@advarra.com](mailto:adviser@advarra.com)

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Please reference the following number when contacting the Study Subject Adviser:  
Pro00066989.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

## **WILL MY MEDICAL INFORMATION BE KEPT CONFIDENTIAL?**

### **GENERAL STATEMENT ABOUT PRIVACY**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed and dated consent form and some of your research test will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation). California regulations require reporting **all** positive HIV test results (not just new cases) to the county public health department. The required report includes CD4+ count (or T-cell count), viral load, and viral genotype. The San Francisco Department of Public health may share the results with the participant's home county health department if they do not live in San Francisco County.

California regulations require laboratories that **new** cases of TB, hepatitis C, or hepatitis C, and COVID-19 to the county health department. All COVID-19 test results (positive, negative, or inconclusive) must be reported. The reports include details like: participant name, social security number, and other identifying information. Information about these infections is used to track these diseases statewide and nationwide. Other than this required reporting, test results will be treated confidentially by the study staff and personally identifying information will not be reported to other departments or agencies. For a full list of reportable conditions, go to the following link:

<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf>

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

GS-US-457-6411

Participant Information and Informed Consent Form

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor Gilead Sciences, Inc
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)
- Representatives of the Office of Human Research Protections (OHRP)
- Advarra IRB

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

**Authorization to Use and Disclose Records**

During this study your study doctor, nurses and other study site personnel will record information about you, your health and your participation in the study on forms provided by Sponsor. These forms are known as case report forms. You will not be able to participate in this study if you do not consent to the collection of this information about you.

The information collected about you, will be held by the study site, Sponsor and Sponsor's authorized representatives. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records or samples your study doctor provides to Sponsor or Sponsor's authorized representatives. Instead, you will only be identified by a code. The code is used so that your study doctor can identify you if necessary.

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- Checking your suitability to take part in the study,
- Monitoring your treatment with the study drug,
- Comparing and pooling your treatment results with those of other participants in clinical studies,
- Establishing whether the study drug meets the appropriate standards of safety set by the authorities,
- Establishing whether the study drug is effective,
- Supporting the development of the study drug,
- Supporting the licensing application for regulatory approval of the study drug anywhere in the world,
- Supporting the marketing, distribution, sale and use of the study drug anywhere in the world, and/or
- As otherwise required or authorized by law.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

If necessary for these purposes, the Sponsor may share your information with its affiliates, people and companies with whom the Sponsor works, and regulatory or other governmental agencies. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by federal privacy law.

As explained in this consent form, your participation in this study is voluntary and you may withdraw from the study at any time by informing your study doctor. By signing this consent, you authorize the collection and use of information about you as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you by informing your study doctor in writing at the address listed on the first page of this consent form. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. The Sponsor will need to keep and use any research results that have already been collected. The Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the study or to revoke your authorization for the collection and use of information about you will not result in any penalty or loss of access to treatment or other benefits to which you are entitled. This authorization has no expiration date, unless and until you revoke it.

In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.

If you have any questions about the collection and use of information about you, you should ask your study doctor.

Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

## 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 this form.

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Printed Name of Participant

---

Signature of Participant

---

Date

## **WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY?**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study is NCT06029972.

A description of this clinical trial will also be available on <https://www.clinicaltrialsregister.eu>, as required by EU law. This website will not include information that can identify you. At most, this website will include a summary of the results.

A summary of the results in a format that is easily understood (also known as plain language summary [PLS]) may also be available on <https://www.gileadclinicaltrials.com>. Information included in the PLS will not identify you. This information will only be available at the end of the trial.



Version 4.1.2 Dated 08Feb2024

(based on Master Main Informed Consent Form Version 4.0 Dated 01Sep2023)

USA Main Informed Consent Form

Participant Information and Informed Consent Form

GS-US-457-6411

**AGREEMENT TO BE IN THE STUDY**

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

By signing this informed consent form, I acknowledge the following:

- (1) I have carefully read and understand the information in this form.
- (2) The purpose and procedures of this research study have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
- (3) I have been informed of the drugs and procedures of the study that are being tested. I have been informed of possible risks as a result of taking part in this study that could happen from both known and unknown causes.
- (4) I understand that I am free to withdraw my consent and to stop my participation in this study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me.
- (5) I understand that stopping the study will not impact my medical care and treatment options.

You will be asked to sign and date a separate form authorizing access, use, creation, or disclosure of health information about you.

**Participant**

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Participant Printed Name

Signature

Date

**Person Obtaining Consent**

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Printed Name & Title

Signature

Date