Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

USC Clinical Trials

Title	A Phase 2, Randomized, Open-Label Study Evaluating the Safety and Efficacy and of Magrolimab in Combination with Nab-Paclitaxel or Paclitaxel versus Nab-Paclitaxel or Paclitaxel in Previously Untreated Patients with Metastatic Triple-Negative Breast Cancer
Protocol Number	GS-US-586-6144
Project Sponsor	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404; Gilead Sciences Pty. Ltd. Level 6, 417 St Kilda Road Melbourne VIC 3004
Coordinating Principal Investigator/ Principal Investigator	Dr Brenton Seidl
Location	USC Clinical Trials/ Sunshine Coast Haematology and Oncology Clinic (SCHOC) 10 King Street Buderim QLD 4556

1 Introduction

You are invited to take part in this research project. This is because you have triple negative breast cancer. The research project is testing a potential new treatment for triple negative breast cancer. The new treatment is called Magrolimab in combination with either nab-paclitaxel or paclitaxel for the treatment of metastatic triple-negative breast cancer (mTNBC) for patients with untreated mTNBC.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.
You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to evaluate Magrolimab in combination with either nab-paclitaxel or paclitaxel for the treatment of metastatic triple-negative breast cancer (mTNBC) for patients with untreated mTNBC.

This study is split into two parts. The initial phase (safety run-in) is to confirm a safe dose of magrolimab in combination with either nab-paclitaxel or paclitaxel, and the second part (phase 2) is to see if magrolimab in combination with nab-paclitaxel or paclitaxel is effective in treating mTNBC.

Other purposes of this study include determining the quantity of magrolimab in the blood, your quality of life and the side effects these drugs have on the body.

Magrolimab is an experimental drug because it has not yet been approved by any regulatory authority for cancer treatment or treatment of any other disease.

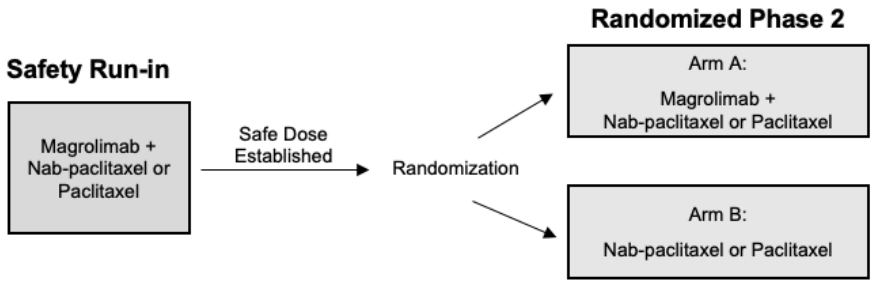
Nab-paclitaxel is currently approved in Australia as treatment of Metastatic Breast Cancer and other cancers.
Paclitaxel is currently approved in Australia as treatment of Metastatic Breast Cancer and other cancers.

3 What does participation in this research involve?

If you agree to take part in this study, you will be one of about 110 participants in this study. The study will take place at about 50 locations worldwide. 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 enrolment into the study. In order to manage the total study enrolment, Gilead, at its sole discretion, may stop screening and/or enrolment at any site or the whole study at any time.

If you are eligible for study participation, you will be placed in one of two cohorts – the Safety Run-in Cohort or the Randomised Cohort (phase 2). Participants in the Safety Run-in Cohort will receive magrolimab in combination with nab-paclitaxel or paclitaxel, to determine the safe dose of the two drugs combined. Once a safe dose has been established, additional participants will be offered the second part of the study – the Randomized Cohort. The Randomized Cohort will be divided into two groups, Arm A and Arm B. In Arm A, participants will receive magrolimab with either nab-paclitaxel or paclitaxel. In Arm B, participants will not receive magrolimab but will receive either nab-paclitaxel or paclitaxel alone. Randomized means the study treatment you take will be chosen by chance – like flipping a coin. You will have 1 out of 2 chances to receive magrolimab with either nab-paclitaxel or paclitaxel and 1 out of 2 chances to receive either nab-paclitaxel or paclitaxel alone.



This is a phase 2 open-label study. Open-label means you and your study doctor will know what study drug(s) you will be taking. Your study doctor will inform you if you are assigned to the Safety Run-in, or in the Randomized Phase 2 (Arm A or Arm B) part of the study.

Magrolimab, will be supplied by Gilead Sciences Inc. (GSI), which is also the Sponsor of this study. Nab-paclitaxel and paclitaxel will be supplied by the Hospital Pharmacy.

How long will you be on the study?

Taking part in this study will last about 1-2 years, not including the screening visit(s). Your participation in the study, including receiving study treatment, may continue as long as you are tolerating the treatment and your cancer has not progressed or the study is not stopped.

Study treatment will be given in 28-day (4 week) cycles. You will be required to visit the clinic the following number of times while on treatment:

- Cycle 1: 5 times
- Cycle 2: 4 times
- Cycle 3 and beyond: 3 times per cycle until you stop study treatment

After completing treatment, you will be required to visit the clinic for:

- End of Treatment visit: 1 time
- Safety Follow-up visit: You will receive a phone call to check your status and to assess if you need to return to the clinic, if you are experiencing side effects. This may be only 1 time but could be more than once if your study doctor decides it is necessary to monitor the side effect(s) until it resolves or becomes stable.

Female participants who can get pregnant will to return to the clinic 6 times after the End of Treatment visit - once a month for 6 months for a pregnancy test. You may discuss the option of doing a home pregnancy test and reporting the results monthly instead of coming to the clinic, if your study doctor will allow it.

If you stop treatment before your cancer gets worse (disease progression), you will continue to have CT or MRI scans (radiology scan of your tumour) after your safety follow up. You will need to go to the clinic for your pre-progression visit. Scans will be collected approximately every 8 weeks until disease progression or you start another cancer treatment, whichever is earlier.

What will happen at each study visit?

The table below shows what will happen each time you visit the clinic. The procedures or tests are described after the table:

Safety Run-in and Phase 2 **(magrolimab and nab-paclitaxel/paclitaxel):**		Cycle (28 days)											
		Cycle 1					Cycle 2				Cycle 3		
Procedure (what will happen)	Screening (To see if you qualify)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15
Review and sign Informed Consent Form (ICF)	X												
Review your medical and cancer history	X												
Review any changes in your health and medications since last visit	X	X	X	X	X	X	X	X	X	X	X	X	X
Review medications you are taking	X	X	X	X	X	X	X	X	X	X	X	X	X
Full physical examination (including height & weight)	X	X		X	X	X	X		X		X		X
Complete quality of life questionnaires (phase 2 only)		X					X				X		
Measure your vital signs: (blood pressure, heart rate, breathing rate, and temperature)	X	X		X	X	X	X	X	X	X	X	X	X
Take blood and urine samples for routine health tests (chemistry, hematology, endocrine, coagulation, blood & urine pregnancy test for women who are able to have children)	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood Type and Cross Match Testing	X												
Blood sample for pharmacokinetic (PK) testing		X		X			X				X		
Blood sample for immunogenicity (antidrug antibodies) assessment		X					X				X		
Blood samples for genomic (study of genes) research		X											
Blood sample for biomarker research*	X	X		X	X		X				X		
Approximate total amount of blood taken	3 Tbsp. /44.3mL	5.5 Tbsp. /82.5ml	0.2 Tbsp. /2ml	4.5 Tbsp. /66.5ml	4.5 Tbsp. /64ml	0.3 Tbsp. /4.5ml	4.5 Tbsp. /64.5ml	0.3 Tbsp. /4.5ml	0.3 Tbsp. /4.5ml	0.3 Tbsp. /4.5ml	4.5 Tbsp. /64.5ml	0.3 Tbsp. /4.5ml	0.3 Tbsp. /4.5ml
Collect stool sample		X									X		
ECG (single)	X												
Tumour Biopsy	X										X		
Tumour Imaging (using either a CT scan, PET CT scan or MRI)	X										X Q8W		

Receive magrolimab premedication		X		X									
Receive magrolimab infusion in clinic		X		X	X	X	X	X	X	X	X		X
Receive nab-paclitaxel/paclitaxel infusion in clinic		X		X	X		X	X	X		X	X	X

*For serum and plasma biomarkers, whole blood RNA, and immunophenotyping assay, an additional sample will be collected 4 hours post dose on Cycle 1 Day 8.

Procedure or Test	Description
Health and medication History	Your complete medical and surgical history including medication taken will be reviewed and taken by the study doctor or a qualified staff member. This will include your cancer disease details and prior treatment(s), Human Immunodeficiency Virus (HIV) and Hepatitis B and/or C status.
Changes in your health and medications you are taking	At each visit, the study doctor or qualified staff will review and document any health issues you may have recently experienced. Any medicine you are currently taking will also be documented.
Physical Examination	A complete (full) physical exam will be performed by the study doctor or a qualified staff member. Depending on the study visit, your doctor may not conduct a complete physical exam, but will conduct a focused exam.
Vital Signs and Weight	A measurement of your blood pressure, heart rate, breathing rate, and temperature will be taken by the study doctor or a qualified staff member. Your weight will also be measured (at screening only).
Health Related Quality of Life Questionnaires	You will be asked to answer some questions about your health from your point of view
ECG (Electrocardiogram)	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.
CT/PET CT or MRI scan	A scan to assess the study drug efficacy (how well the study drug is working). You will be asked to lie still on a movable table so that a CT/PET-CT or MRI machine can take images. A CT/PET-CT scan uses radiation to produce images. An MRI machine uses magnets to produce images.
Archival Tissue or Tumour biopsy	Archival tissue (tumour tissue that was previously collected and stored) may be obtained by your physician. If archival tissue is not available, a pre-treatment biopsy will be conducted. This procedure will be done to get a sample of tissue from your tumour(s) and examined under a microscope or tested to determine whether disease is present and to understand characteristics of the tumour to better understand why participants respond or do not respond. After two cycles of treatment another tumour biopsy will be done to get additional tumour tissue to assess biomarkers, study drug response and to better understand the biology of your cancer.

Lab Tests and Biologic Sample Collection	Description
Study question tests	Samples of your blood, urine, tissue, tumour 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 test	If you are a woman who can get pregnant, a sample of your blood at screening and urine on Day 1 of every cycle will be taken to test for pregnancy. Pregnancy testing will continue after you have stopped treatment, once a month for 6 months. To take part in this study, the pregnancy test must be negative.
Blood Type and Cross Match Testing	Samples of your blood will be tested to determine your blood type and blood compatibility in case you need a transfusion in the future.
Pharmacokinetic test	Samples of your blood will be tested to see how much study drug is in your body and what your body has done to the study drug.
Anti-Drug antibody test	Samples of your blood will be tested to see how much study drug is in your body and to determine if your body is developing any resistance to the study drug.
Biomarker test	Samples of your blood and tumour will be used to help answer the study questions, better understand the disease, and how the study drug affects your disease.
Stool Sample	A sample of your stool will be collected, at home, to assess microbiome (genetic material of all everything that lives on and inside the human body)
Genomic and Genetic Testing	Genomics is the study of genes and their function (factors inherited from our parents and how they work). Tumour and blood samples will be collected to find genetic changes related to your cancer. DNA and RNA from your samples may be examined to explore biomarkers and how they may affect clinical response or toxicity.
Optional future research tests	If you agree, any of your leftover (including unused or remaining) stored blood, stool, or tumour samples may be used for future testing to help answer questions that are not part of the main study. If you do not agree, you can still take part in the main study. More information, including the potential research benefits of this testing, can be found at the end of this informed consent form.

Study Drug	Description
Take pre-medication	At the visits marked on the table, you will be required to take pre-medication. The premedication will be oral or given to you by IV at the clinic by a qualified staff member. During the first two weeks of receiving the magrolimab dose administration you will receive acetaminophen/paracetamol and antihistamines (medications that relieve the symptoms of allergies) or similar medications to help prevent potential infusion reactions (the infusion reactions are detailed in the risk section of this consent form).
Get study drug: Magrolimab and/or either nab paclitaxel or paclitaxel	At the visits marked on the table, you will be given study drug at the clinic. The study drugs will be given to you by intravenous (IV) infusion (delivery into the vein) at the clinic by a qualified staff member. For margolimab dosing you will start at the low dose (called “priming dose”) of 1 mg/kg during the first week (Cycle 1 Day 1). The dose of magrolimab will then be increased to 30 mg/kg for Cycle 1 Days 8, 15 and 22 as well as Cycle 2 Days 1, 8, 15, 22. From Cycle 3 Day 1 onwards the dose will be 60 mg/kg

Post treatment assessments:

	EOT Visit	Safety Follow-up visit	Pre-progression visit	Survival follow up
	Within 7 days after last dose or EOT decision	30 days after last dose	After safety follow up until disease progression	Every 2 months after safety follow up
Procedure (What will happen)	±7 days	±7 days		
Review any changes in your health and medications since last visit	X	X		
Measure your vital signs: (blood pressure, heart rate, breathing rate, and temperature)	X			
Physical examination	X			

Blood sample for biomarker research	X			
Take blood samples for routine health tests (chemistry, hematology)	X			
Urine pregnancy test (for women who are able to have children)*	X	X	X	X
Blood sample for pharmacokinetic (PK) testing	X			
Blood sample for immunogenicity (antidrug antibodies) assessment	X			
Approximate total amount of blood taken	0.8 Tbsp. / 11.5ml			
Complete quality of life questionnaires (phase 2 only)	X			
Tumour imaging	X		X	
Review any new anticancer therapies you are taking		X	X	X
Survival follow up				Every 2 months

*Urine pregnancy test will be performed monthly for 6 months after the end of treatment.

Visit lengths

The length of your visit will be dependant upon the cycle, day and treatment arm. Specifically:

Visit	Screen-ing	C1 D1	C1 D2	C1 D8	C1 D15	C1 D22	C2 D1	C2 D8	C2 D15	C2 D22	C3 D1	C3 D8	C3 D15
Length (hours)	2hrs	8hrs	Local lab visit for blood draw	8hrs	8hrs	5hrs	8hrs	8hrs	8hrs	5hrs	6hrs	3hrs	6hrs

Dosing Delay

If your magrolimab dosing is delayed by at least two weeks or more, depending on the dose of magrolimab you are taking, you will be required to start taking magrolimab again at the low dose of 1 mg/kg (priming dose). The dose will be increased gradually back to your normal dose over a period of 4 weeks. This means you will need to come to the clinic at least once every week for 4 weeks similar to the schedule for cycle 1.

Continuing Treatment After Disease Progression

If your scans show that your cancer has progressed, you may stay on treatment until your progression is confirmed by additional scans at least four weeks later. You may

also continue treatment if your study doctor considers the study treatment is still benefitting you and you do not have, nor developed, any of the conditions below:

- Signs or symptoms of significant progression of your cancer
- Decline in your ability to perform daily activities
- Rapid disease progression or other safety risk
- You require urgent alternative treatment

Continuing on treatment after progression is not standard in the treatment of cancer, but some drugs that modify the immune system such as the drugs used in this study can have a delayed effect on tumour growth.

How much will treatment cost me?

The study drug used in this study will be given to you free of charge. All study visits and fees for lab tests and procedures that are part of this study will be provided at no cost to you.
You or your usual health care payer will be responsible for any other health care costs.

Will I be paid to be part of this study?

You will not be paid to take part in this study. You will be reimbursed a flat rate of $100 per visit for any travel and other expenses incurred in participating in the study.

4 What do I have to do?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you.

- You must not get pregnant or get someone pregnant during this study.
- It is very important that you tell your study doctor all of 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 while in the treatment phase of this study. Please consult with your doctor to see what medications you may not take.
- 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.
- To carry your Participant Card with you at all times during study participation.

5 Other Relevant Information About the Research Project

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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. A description of this clinical study will also be available on https://eudract.ema.europa.eu/. This website 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.

6 Do I have to take part in this research project?

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.

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(s) 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(s). If your study drug(s) is stopped, your study doctor will closely monitor your overall health.

If you stop participating in this study, information about whether you are alive or deceased may be collected every 2 months. This information may also be gathered from public records such as government census or death records.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. 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 treatment for your disease. These treatments include those that are already approved and sold.
You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

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 fighting a disease.

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

9 What are the possible risks and disadvantages of taking part?

Magrolimab Common Side Effects
Magrolimab is currently not approved and has not been previously administered to patients with mTNBC nor in combination with paclitaxel/nab-paclitaxel, the safety profule in this population is therefore not known. Magrolimab is being studied in people with multiple oncology (cancer) indications, including Non-Hodgkin's Lymphoma, Myeloid malignancies, Colorectal Cancer, and Ovarian cancer.

There are risks involved with taking magrolimab.

In previous studies of magrolimab, the most common drug-related adverse (bad or harmful) events in ≥ 10% of 568 people who received at least one dose of magrolimab were:

- Fatigue (43.0%)
- Anaemia (abnormally low number of red blood cells) (40.8%)
- Headache (36.4%)
- Nausea (34.7%)
- Fever (30.8%)
- Infusion related reaction (allergic reaction to drugs while it is being given into your vein or shortly thereafter) (29.6%)
- Diarrhea (28.7%)
- Constipation (27.8%)
- Chills (25.7%)
- Shortness of breath (22.2%)
- Vomiting (21.8%)
- Cough (20.8%)
- Decreased appetite (20.4%)
- Abdominal pain (17.3%)
- Back pain (16.5%)

- Hypokalaemia (decrease of potassium in the blood) (15.5%)
- Dizziness (lightheadedness) (14.6%)
- Blood bilirubin increased (increase of orange-yellow pigment that occurs normally when part of your red blood cells break down) (14.3%)
- Platelet count decreased (14.3%)
- Febrile Neutropenia (a condition marked by fever and low numbers of neutrophils (a type of white blood cell that fights infection) in the blood) (13.7%)
- Thrombocytopenia (abnormally low platelets in the blood) (13.2%)
- Red blood cell agglutination (red blood cells sticking together when viewed on a glass slide under the microscope) (12.0%)
- Hypotension (low blood pressure) (10.9%)
- Oedema Peripheral (swelling and fluid retention in the arms and legs) (10.4%)
- Pruritus (itchy skin) (10.2%)

Anaemia and haemolysis (destruction of red blood cells)
The study drug magrolimab attaches to red blood cells. When it attaches to old red blood cells, some of the old red blood cells may die, causing anaemia, especially at the beginning of the treatment. Anaemia is detected by a blood test counting the red blood cells, and can cause pale skin, fatigue and loss of energy, shortness of breath, low blood pressure and/or rapid heartbeats. Anaemia and haemolysis (haemolytic anaemia) may be life-threatening and could be fatal. If it is severe, your doctor may recommend a blood transfusion to increase the number of your red blood cells and/or stop treatment altogether with magrolimab. It is important that you inform the study doctor about any past known or suspected cardiovascular (heart) disease and any related symptoms, including but not limited to, chest pain, difficulty breathing, and swelling of the lower limbs before participating in the study. These conditions may increase your risk of side effects from anaemia.

Pneumonitis/Respiratory Distress/Acute Respiratory Failure
Pneumonitis (inflammation of the lungs), associated with respiratory distress/failure (severe difficulty in breathing) has been reported in a number of patients receiving magrolimab. Your study doctor will monitor you carefully for any respiratory symptoms and will take proper medical action if any such situations arise. Please contact your primary care doctor immediately if you experience symptoms of shortness of breath, chest pain or cough.

Infusion-Related Reactions

Magrolimab may cause side effects similar to an allergic reaction while it is being given into your vein or shortly after it is given, especially during/after the 2 first doses. These reactions could include symptoms such as fever, chills, back pain, nausea, vomiting, headache and shortness of breath. To date, these infusion-related reactions in general were observed to be mild to severe, although life-threatening reactions have occurred. If you experience these symptoms, your study doctor may slow down, interrupt, or even stop the delivery of magrolimab into your vein and give you drugs to treat them. In some cases, you might be admitted to the hospital for treatment and monitoring. You will receive medications before your first four treatments of magrolimab in an attempt to minimize the risk of occurrence of these signs. If you have experienced infusion reactions, your study doctor may prescribe premedication prior to your next treatment with magrolimab.

For your safety, the study doctor will monitor you for these events. For example, you may have your blood pressure, pulse, body temperature, and respiratory rate monitored before the magrolimab infusions. If you are receiving magrolimab and experience a reaction that could be related to magrolimab, we may stop the infusion.

Hemagglutination/red blood cell agglutination (red blood cells sticking together when viewed on a glass slide under the microscope)
Studies in test tubes have shown that magrolimab can make the red blood cells sticky. This may be a potential concern because sticky red blood cells in the body can cause tiny clots, which may block normal blood flow in the smallest blood vessels and cause ischemia (decreased flow of blood and oxygen supply to tissues).

Participants treated with magrolimab have been found to have clumping of red blood cells on a glass slide under the microscope; however, most of these participants did not have side effects (like blocked blood flow) that could be directly linked to that observation.

Anti-Drug Antibody Reaction
In some participants, treatment with magrolimab causes the body's immune system to develop special antibodies directed at magrolimab. These antibodies can affect how magrolimab is handled by your body. Antibodies are proteins made in the body that respond to a substance that is foreign to the body. If you develop these special antibodies, it may affect your body's ability to respond to magrolimab in the future and might produce side effects including infusion reactions or may affect your kidneys. Blood samples will be drawn to monitor for the development of these antibodies during study treatment and 7 days after your last infusion of study drug.

Other Laboratory Abnormalities

Thrombocytopenia (abnormally low platelets in the blood) was observed in at least 1 out of 10 participants treated with magrolimab. Platelets are colourless blood cells that help blood to clot. Low platelets could lead to bleeding. If your platelets go too low, your doctor may prescribe appropriate treatment.

Other laboratory abnormalities experienced by at least 1 out of 10 participants included hyperbilirubinemia (increase of orange-yellow pigment that occurs normally when part of your red blood cells break down, also known as jaundice) and hypokalaemia (decrease of potassium in the blood).

Interactions with Other Drugs
Magrolimab may have some side effects that may overlap with some of the side effects caused by other medications that also stimulate the immune system. It may be dangerous to take both/all of these drugs at the same time. It is important to tell your doctor the last time you took any.

Risks Related to Blood Type and Cross Match Testing
Based on studies in the laboratory using human blood samples, magrolimab may interfere with some of the tests used to determine your blood type. This may require that special additional testing be performed on your blood if you were to need a red blood cell transfusion for any reason. The primary risk of interference of the blood type and cross match results is that you could receive blood that is the wrong type, during a transfusion, resulting in a serious and life-threatening reaction or death.
For any non-emergency red blood cell transfusion, you will be required to come to the study site where the appropriate testing can be performed. In the event of an emergency and you are taken to another hospital, the emergency doctors should contact the study doctor immediately.

You will be informed in a timely manner of any new information that may change whether or not you want to continue to take part in this study.

Please talk to your study doctor for more details on side effects.

Nab-Paclitaxel Common Side Effects
The most common drug-related adverse (bad or harmful) events in greater than or equal to 10% of 229 people with breast cancer, based on the Australian Product Information nab-paclitaxel package insert include:

- Hair Loss (90%)
- Decreased white blood cell count (80%)
- Numbness, tingling, pain, or weakness in the hands or feet (71%)
- Abnormal heartbeat (60%)

- Feeling tired and/or weak (47%)
- Muscle aches/Joint pain (44%)
- Changes to your liver function tests (39%)
- Low red blood cells count (Anaemia) (33%)
- Nausea (30%)
- Diarrhea (27%)
- Infections (24%)
- Vomiting (18%)
- Shortness of breath (12%)
- Fluid retention/swelling (Oedema) (10%)

Please talk to your study doctor for more details on side effects or see the nab-paclitaxel package insert for more information.

Paclitaxel Common Side Effects
The most common drug-related adverse (bad or harmful) events in greater than or equal to 10% of 225 people with breast cancer, based on the Australian Product Information paclitaxel package insert include:

- Hair loss (94%)
- Decreased white blood cell count (82%)
- Numbness, tingling, pain, or weakness in the hands or feet (56%)
- Abnormal heartbeat (52%)
- Feeling tired and/or weak (39%)
- Muscle aches/Joint pain (49%)
- Changes to your liver function tests (32%)
- Low red blood cells count (Anaemia) (25%)
- Nausea (22%)
- Infections (20%)
- Diarrhea (15%)
- Vomiting (10%)

Please talk to your study doctor for more details on side effects or see the paclitaxel package insert for more information.

BLOOD DRAWS
Collecting a blood sample from a vein may cause pain, bruising, light-headedness, fainting, and very rarely, infection at the site of the needle stick.

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 have your chest shaved for this procedure.

TUMOR/ TISSUE BIOPSY
Risks and complications of tumour biopsy may include:

- Pain, bruising and discomfort located at or near the biopsy site
- Bleeding, swelling or scarring at the biopsy site
- Possible internal bleeding for up to a few hours after the procedure
- Infections at the biopsy site (where the needle is inserted)
- Puncture/damage of internal organs (depending on the location of the tumour)
- Allergic reaction to the anaesthetic

The risks and complications of tumour biopsy mentioned above is by no means a complete list. Your Study Doctor will discuss all the risks and complications of the biopsy with you.

You may be asked to read, understand and sign a separate consent for a tumour biopsy by your Study Doctor. Your study doctor can explain additional risks about the way the tumour biopsy will be taken.

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 to your study doctor.

MAGNETIC RESONANCE IMAGING (MRI) OR COMPUTED TOMOGRAPHY (CT)/PET-CT SCANS
MRI or CT/PET-CT scanners use special equipment to take pictures of the inside of your body. The MRI or CT/PET-CT scanner is a large machine shaped like a doughnut and has a bed in the middle of the circle that you lie on. The bed can slide backwards and forwards through the hole of the “doughnut.” Pictures of your internal organs are taken as you move through the machine. MRI or CT/PET-CT scans will be used to follow your treatment.

If the doctor uses MRI scans, you will be exposed to powerful magnetic fields. There are no known risks resulting directly from exposure to these magnetic fields. However, it is possible to feel muscle twitches and tingling sensations or a slight increase in body temperature during the test. Participants who have metal devices in their bodies such as pacemakers, certain aneurysm clips, shrapnel, or surgical devices might be at increased risk from MRI scans. If you have any metal in your body, you should inform the

technologist before entering the magnet room. Because of the strong magnetic field associated with the scanner, it is rare, but possible, that a metallic object could fly through the air toward the scanner and hit you. To reduce this risk, you will need to remove metal from your clothing or pockets when in the MRI scanning room. The MRI scanner produces tapping sounds that can reach very loud levels. To avoid any discomfort from this noise, you can wear earplugs or headphones that are available in the MRI scanning room.

This research study involves exposure to a very significant amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 522 mSv. It should be noted that minimum latency period for radiation induced cancer is about 2-3 years and is typically more than 7 years.

Some people have reported feeling anxious or claustrophobic (like being trapped) during the MRI or CT/PET-CT scans because they are performed in a narrow enclosed space. You can ask for the scan to be stopped at any time if you cannot stand being in the scanner. Medicine can also be provided to relieve anxiety during these scans.

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:

- rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

There are side effects that are not known or happen rarely when participants take these 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.

If, as a result of being in this study, you become ill or are injured, please immediately contact your study doctor. She or he will then give you all necessary information and

treatment and will inform the trial sponsor. In the case of a serious and rapidly escalating adverse reaction contact emergency services on 000. Ensure that you have your emergency card with you so the study doctor can be contacted as necessary.

PREGNANCY AND BREASTFEEDING

Magrolimab is not recommended in pregnancy as the effects of magrolimab on an unborn baby are not known. Nab-paclitaxel and paclitaxel can cause harm to an unborn baby, and breastfeeding while taking nab-paclitaxel or paclitaxel is not advised. Therefore, if you are pregnant or breastfeeding you cannot take part in this study.

If you or your partner becomes pregnant while you are taking magrolimab, nab-paclitaxel or paclitaxel you must 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 or your partner's study doctor will not be responsible for the costs related to your pregnancy, delivery, or care of your child.

In the event you become pregnant during the study, you will be immediately withdrawn from the study. You will be invited to give consent to allow access to information regarding any pregnancy and its outcome for the purpose of determining any effects from the study.

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

For women:
Acceptable birth control methods for use in this study are:

Complete abstinence from intercourse.

Or

Consistent and correct use of 1 of the following methods of birth control listed below:

- Non-hormonal intrauterine device (IUD)
- Hormonal IUD (must be used in addition to a barrier method)
- Bilateral tubal occlusion (upon medical assessment of surgical success)
- Vasectomy in the male partner (upon medical assessment of surgical success)

Or

If you wish to use a hormonally-based method, you must use it in conjunction with a barrier method, preferably a male condom. Hormonal methods are restricted to those associated with the inhibition of ovulation. Hormonally-based birth control methods and barrier methods permitted for use in this study are as follows:

- Hormonal methods (each method must be used with a barrier method, preferably male condom)
  - Oral contraceptives (either combined or progesterone only)
  - Injectable progesterone
  - Transdermal contraceptive patch
  - Contraceptive vaginal ring
  - Subdermal contraceptive implant
- Barrier methods (each method must be used with a hormonal method)
  - Male condom (with or without spermicide)
  - Female condom (with or without spermicide)

The duration of acceptable birth control methods in this study should start from the screening visit until 6 months after the last dose of the latest administered study drug.

Inclusion of methods of birth control in this list of permitted methods does not imply that the method is approved in any country or region. Methods should only be used if locally approved.

You must also refrain from egg donation, cryopreservation of cells (freezing of eggs), and in vitro fertilization during treatment and until the end of the birth control requirement.

For men:
If you have a female partner of childbearing potential, you must use condoms during treatment and until 6 months after last dose of any study drug. If your female partner of

childbearing potential is not pregnant, use of any locally approved birth control method should also be considered.

You must also refrain from sperm donation and cryopreservation of cells (freezing of sperm) during treatment and until the end of the birth control requirement.

Birth control methods that are unacceptable for use in this study include: periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and lactational amenorrhea method (LAM). A female condom and a male condom should not be used together.

If you are sexually active, please speak with your study doctor about the best method of birth control for you during this study.

10 What will happen to my test samples?

Some of your blood and tissue samples taken at screening, Day 1 of each cycle, Cycle 1 Day 8, Cycle 1 Day 15 and the end of treatment visit will be sent to: Precision for Medicine, Melbourne VIC 3004, Australia or Covance (Asia) Pte. Limited, Singapore and Covance Central Laboratory Services Sàrl, Switzerland, or PPD Lab, Middleton, WI 53562, USA. Your stored samples and the information collected about you during the study may be used by the Study Sponsor, its research partners or companies, to help answer study questions. At the end of this study, these samples may be held in storage by Gilead for up to for up to 15 years. 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.

Tumour Samples for DNA Testing
Samples from your tumour biopsy will be stored. Your stored samples and the information collected about you during the study may be used by the Study Sponsor or its research partners to look for genetic changes in your tumour. At the end of this study, these samples may be held in storage at Greenfield Biorepository, Covance Biorepository, Greenfield, Indiana, USA by Gilead for up to for up to 15 years. Genetic changes are when DNA in a gene is damaged in a way that changes the message carried by that gene. Genetic changes can sometimes cause cancer and can sometimes cause cancer to come back after it has gone away. These genetic changes are only found in tumour cells, not the normal cells in your body.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug/treatment/device being shown not to be effective

• The drug/treatment/device being shown to work and not need further testing
• Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

15 What happens when the research project ends?

You will be contacted by phone every 2 months (for up to 3 years) from the date of the safety follow-up visit or last pre-progression visit, whichever is applicable. This will be to check on your health status and information on any new cancer treatments. Your primary doctor or family may be contacted by the study doctor in order to obtain this information in case you cannot be reached. In the event that your primary doctor or family cannot be reached, the study doctor may search through publicly available records to obtain survival information.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the Consent Form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. 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 doctor provides to Sponsor or Sponsor's authorised representatives. Instead, you will only be identified by a code. The code is used so that your doctor can identify you if necessary. Your information will be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

In the case of data that identifies you, or from which your identity may be ascertained, an entity subject to Australian privacy laws that has collected your information must take reasonable steps to ensure that an overseas recipient handles the information in accordance with any relevant Australian privacy principle (unless an exemption applies). If you have any questions about this, direct them to the Principal Investigator.

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

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree

to the study team accessing your health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Gilead Sciences, Inc. the institution relevant to this Participant Information Sheet, USC Clinical Trials, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Sponsor may communicate information to affiliates of Sponsor, people and companies with whom Sponsor works, and regulatory or other governmental agencies. These people, companies, and agencies may be located in your country, the United States, and other countries that are outside of your country. Some countries outside of your country may not offer the same level of privacy protection as you are used to in your country. However, the information will be treated as confidential and securely stored.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information. However, by signing the consent form you agree that you will not be able to have access to your personal health information related to this study until the study is over. This is done to maintain the scientific integrity of the study. After the study is complete, you can obtain access to your information through your Study Doctor.

Any information obtained for the purpose of this research project and for the future research described in this Section that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

You may revoke your authorisation for the collection and use of information about you by informing your study doctor in writing. If you withdraw from the study or if you revoke you authorisation for the collection and use of information about you, your participation in the study will end and the study personnel will stop collection information from you. Sponsor will need to retain and use any research results that have already been collected. Sponsor must do this to comply with its legal obligation and to maintain the

scientific integrity of the study. This authorisation for the collection and use of information about you has no expiration date, unless and until you revoke it.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:
• The pharmaceutical industry has set up a compensation process, with which Gilead, the Sponsor of this research project has agreed to comply. Details of the process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please contact Lucas Litewka, Director, USC Clinical Trials via email at llitewka@usc.edu.au or on 07 5456 3797.
• You may be able to seek compensation through the courts.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

18 Who is organising and funding the research?

Gilead Sciences, Inc (pharmaceutical company), will be organising and funding this study. Gilead Sciences, Inc will pay your study doctor and/or the study site to cover their costs of conducting this study. If applicable, your study doctor will disclose to you any financial links or other interests that he/she may have to the Sponsor.

19 Who has reviewed the research project?

If you have any further questions regarding this study, please do not hesitate to contact Dr(s) Seidl on 07 5456 3797.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

All study participants must be provided with a signed and dated copy of the Participant Information Sheet and Consent Form for their personal records.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor, Dr Brenton Seidl, on 07 5479 0000 or study coordinators at USC on 07 5456 3797, or any of the following people:

After-hours contact: 0435 894 558

In case of an emergency, please seek immediate medical treatment by dialling 000 or attending an emergency department. Please be sure to inform your study doctor at your earliest convenience should you receive treatment by a health care provider outside of the study.

Clinical contact person

Name	Georgina Street
Position	Associate Director
Telephone	07 5456 3798
Email	ctc@usc.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Office of the Chief Operating Officer
Address	University of the Sunshine Coast, Sippy Downs Way, Sippy Downs QLD 4556

Telephone	07 5459 4759

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Bellberry HREC
HREC Executive Officer	Operations Manager
Telephone	08 8361 3222
Email	bellberry@bellberry.com.au

Consent Form

Interventional Study - *Adult providing own consent*

USC Clinical Trials

Title	A Phase 2, Randomized, Open-Label Study Evaluating the Safety and Efficacy and of Magrolimab in Combination with Nab-Paclitaxel or Paclitaxel versus Nab-Paclitaxel or Paclitaxel in Previously Untreated Patients with Metastatic Triple-Negative Breast Cancer
Protocol Number	GS-US-586-6144
Project Sponsor	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404; Gilead Sciences Pty. Ltd. Level 6, 417 St Kilda Road Melbourne VIC 3004
Coordinating Principal Investigator/ Principal Investigator	Dr Brenton Seidl

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I am 18 years of age or older.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to USC Clinical Trials concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

USC Clinical Trials

Title	A Phase 2, Randomized, Open-Label Study Evaluating the Safety and Efficacy and of Magrolimab in Combination with Nab-Paclitaxel or Paclitaxel versus Nab-Paclitaxel or Paclitaxel in Previously Untreated Patients with Metastatic Triple-Negative Breast Cancer
Protocol Number	GS-US-586-6144
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Coordinating Principal Investigator/ Principal Investigator	Dr Brenton Seidl

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with USC Clinical Trials.

Name of Participant (please _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.