INFORMED CONSENT FORM

PROTOCOL TITLE:	**OPEN-LABEL, DOSE FINDING AND EXPANSION PHASE IB STUDY TO EVALUATE THE SAFETY, PHARMACOKINETICS AND CLINICAL ACTIVITY OF RO6870810 AND ATEZOLIZUMAB (PD-L1 ANTIBODY) IN PATIENTS WITH ADVANCED OVARIAN CANCER OR TRIPLE NEGATIVE BREAST CANCER**
PROTOCOL NUMBER:	NP39487
SPONSOR:	F. Hoffmann-La Roche Ltd
NAME OF INSTITUTION:	{Name}
INSTITUTION ADDRESS:	{Address}
NAME OF IRB/EC:	{Name}
IRB/EC APPROVAL DATE:	{Insert date}

Introduction

You are invited to take part in a research study (also known as a clinical trial) with a combination of two drugs called RO6870810 and atezolizumab. Both drugs are being developed for the possible treatment of various types of cancer, among other, cancer of the ovaries or breast.

This document describes information to help you make an informed decision as to whether or not you want to take part in this research study. It explains the purpose of the study, your rights and responsibilities, and what to expect if you participate in the study. Please take time to read the following information carefully. Feel free to talk with your doctor, nurse, family, or friends before deciding.

If you have any questions, you may ask your study doctor, Dr. {Name}, for more explanation.

What is the purpose of this study?

You were selected as a possible participant in this study because you have ovarian or breast cancer.

The purpose of this part of the study is to test the safety of RO6870810 when administered in combination with atezolizumab and to find out what effects, good or bad, these study drugs have on you and your disease. Additionally, the effects of RO6870810/atezolizumab in your body, and particularly in your tumor, will be evaluated. The study also aims to find out if RO6870810/atezolizumab can slow down the growth or possibly shrink your tumor.

The study drugs used in this study act in different ways to prevent tumor cell growth and/or get rid of tumor cells:

- RO6870810 is a drug designed to inhibit expression of genes related to cancer by blocking the action of these genes and by preventing tumor growth or eliminating tumor cells.
- Atezolizumab is a drug that may help your immune system stop or reverse the growth of tumors. Atezolizumab is approved by the U.S. Food and Drug Administration (FDA) for the treatment of bladder cancer and lung cancer and for bladder cancer in Canada.

The combination of RO6870810 and atezolizumab is an experimental drug combination. This means that the Health Authorities have not approved this drug combination for the treatment of ovarian or breast cancer. RO6870810 has been tested in humans. However, this is the first time it will be administered in combination with atezolizumab.

How is the study set up?

This part of the study will be conducted with Groups 2, 3 and 4. For all groups, a treatment cycle is defined as a 21-day treatment cycle from the first day of administration of the study treatment combination, which is called Cycle 1 Day 1. Additionally, Group 2 has a 3-week Run-In period when only RO6870810 is administered. The days when RO6870810 is administered by injection, it is administered for 14 days with a 7-day rest period (i.e., 21-day cycle). When atezolizumab is administered, it is given at the same dose on Day 1 of a 21-Day Cycle by intravenous infusion (see below "*How will the study treatment be administered?"*).

Group 1 was a dose-escalation study, which studied 3 doses of R06870810. This part of the study was completed, and aimed at determining the amount of RO6870810 that is safe to administer in Groups 3 and 4 of the study. It was set up to test the safety and activity of RO6870810 in combination with atezolizumab.

Group 2 was a sequential study where RO6870810 was first administered for 14 days, followed by a 7-day rest period. After the Run-In period was completed, RO6870810 in combination with atezolizumab was administered. The same doses RO6870810 that were tested in Group 1 were tested in Group 2. This part of the study was completed. In this part of the study, approximately 6 extra participants will be included. The dose of RO6870810 that you will receive will be the same as a dose already evaluated in Groups 1 and 2. In this Group, the differences in effects on your body will be investigated, i.e., after RO6870810 has been administered alone versus when it has been administered in combination with atezolizumab.

Who is sponsoring and conducting this research?

This research study is being sponsored globally by F. Hoffmann-La Roche Ltd (hereafter referred to as Roche) of Basel, Switzerland. However, it may be implemented in individual countries by Roche's local affiliates, such as Genentech, Inc. in the United States.

The study is under the direction of Dr. {Name} and the research staff for {Name of Study Site}. Roche is providing financial support to cover the cost of study-specific procedures performed during this study.

Who has reviewed this research?

This study has been approved by {Name of IRB/EC}, an organization that is responsible for protecting the rights and safety of patients who take part in research studies.

What are my responsibilities if I take part in this study?

If you decide to take part in this study, you will be required to:

- Keep your study appointments and complete all study assessments.
- Notify study personnel (i.e., the study doctor or research staff) as soon as possible if you cannot attend an appointment and to schedule a new appointment.
- Inform study personnel about any symptoms, changes in medications, doctor's or nurse's appointments, or hospital admissions that you may have had.
- Follow all the instructions and procedures, including:
  - Do not take any herbal supplements or medications from four weeks before the first dose and throughout the study, unless agreed by your study doctor.
  - Follow the instructions about drinking water and about your meals, as described by your study doctor.
  - Inject RO6870810 as instructed.
  - Complete participant diaries as instructed.

- Agree to not participate in any other research study.
- Inform study personnel if you believe you or your partner might be pregnant.
- Inform study personnel if you change your mind about participating in the study.Inform your primary doctor that you are taking part in this study.
- Keep the study treatments in a safe place, for your use only, and away from children.
- Return all study-related supplies, including any unused study treatments.***{For ex-U.S. sites, include the following if applicable:}*** Carry with you at all times during the study a card that states that you are taking part in this study.

RO6870810 is in early development, adherence to strict sun precautions is essential. Adopting the following simple precautions provides substantial protection against UV radiation:

- Limit time in the midday sun, the sun's UV rays are the strongest between 10 a.m. and 4 p.m. To the extent possible, limit exposure to the sun during these hours. Seek shade when UV rays are the most intense.
- Wear protective clothing: A hat with a wide brim offers good sun protection for your eyes, ears, face, and the back or your neck. Sunglasses that provide 99 to 100 percent UV-A and UV-B protection will greatly reduce eye damage from sun exposure. Tightly woven, loose fitting clothes will provide additional protection from the sun.
- Use sunscreen: Apply a broad-spectrum sunscreen of SPF 15+ liberally and re-apply every two hours, or after working, swimming, playing or exercising outdoors.
- Avoid sunlamps and tanning parlors: Sunbeds damage the skin and unprotected eyes and are best avoided entirely.

It is also possible that the study doctor may schedule extra visits or tests for you, if considered necessary.

How many people will take part in the study?

In Group 1 approximately 15 subjects participated in the study (this part of the study is already completed).

In Group 2 approximately 15 subjects participated in the study (this part of the study is already completed). Six extra participants may be added to this group.

In Group 3 approximately 40 breast cancer participants will take part in this expansion part of the study.

In Group 4 approximately 40 ovarian cancer participants will take part in this expansion part of the study.

How will the study treatment be administered?

RO6870810 will be administered first followed by atezolizumab.

RO6870810 will be administered to you at the dose selected for your assigned cohort and will be calculated based on your weight. RO6870810 will be injected into the fatty layer of tissue between the skin and the muscle (subcutaneous injection). This is similar to how some vaccines are given. During your clinic visits, the study staff may inject the drug or, if you prefer, they may watch you inject the drug into your body. You will be taught how to prepare and where to inject RO6870810 on your body. You (or a caretaker) will give yourself the injections at home, or if this is your choice, an optional mobile nursing service will give you the injections at home. You may also have the option to return to the study site (daily) to have your injections administered by the site staff. Be sure not to inject in the same spot for every dose. RO6870810 will not be administered in the same place of your body as the atezolizumab infusion.

Atezolizumab will be administered to you at the clinic by an infusion that will take about 1 hour. It will be administered directly into your vein once every 3 weeks on Day 1 of each of cycle (a cycle lasts 21 days).

If you experienced an infusion-related reaction (IRR; see Risks and Side-Effects section below) after your first administration of atezolizumab, your Study Doctor may administer/prescribe medication with an anti-histamine and acetaminophen/paracetamol prior to the following administrations. You may also receive additional medication to prevent inflammation (for example, glucocorticoids, corticosteroids).

Before you leave the clinic after each visit, you will be provided with material and instructions on how to administer RO6870810 and how to document your home administrations. You will be given a supply of RO6870810, which you must take as directed for 14 days. The material consists of vial, transfer needle (used to withdraw the medicine from the vial), injection needle and syringe.

You will be provided with a participant diary for RO6870810 at each cycle, and will be told how to complete it. The diary will be reviewed with you at each study visit. In the RO6870810 participant diary, you will be asked to record the date, time, and location of each RO6870810 injection as well as any injection reactions (for example, at the site of injection or more generalized effects). You will need to record any missed doses for RO6870810 with the reason for the missed doses.

In case of side-effects, the start of a new cycle might be delayed for up to 3 weeks for RO6870810 and for up to 5 cycles for atezolizumab.

What is Optional Mobile Nursing for Home Administration of RO6870810 Study Drug?

An optional service for home administration of RO6870810 study drug by a mobile nursing service can be provided the days RO6870810 must be administered at home. Study drug will be administered at approximately the same time every day. A mobile

nursing company called GlobalCare Clinical Trials, Ltd. (GlobalCare) has been hired by Roche. GlobalCare representatives will talk with study research staff and arrange for a qualified home nurse who is trained on how to administer RO6870810 study drug by injection.

If you choose to have the mobile nursing service provide your injections, the study research staff will provide the home nursing company (GlobalCare) with your information (such as your name, address, and contact information). The mobile nursing company will contact you to arrange a study-compliant visit schedule that is convenient for you based on instructions from your study doctor. If for any reason you cannot make this (these) visit(s), please contact the home nursing company immediately, and the home nurse will work with you and your study site to make other arrangements for the visit.

Am I guaranteed to receive study drug?

Yes, all participants will receive both study drugs.

The treatment you receive may prove to be less effective or to have more side effects than other available treatments for your disease.

Will I know what I am receiving?

Both you and your study doctor will know which treatment you receive.

If you agree to participate and meet all of the study requirements, your study doctor will explain to you which Group of the study you are assigned, including the study medications and doses you will receive.

How long will I be in the study?

If you qualify and choose to participate, your total length of time in the study will include the screening, dosing period(s), safety follow-up visit and long-term follow-up (visit or telephone call). The exact length of time will be variable.

During this study, you will have several visits. Some visits may last for 5 to 10 hours. Some procedures will be the same as your regular care for your cancer and some procedures will be just for this study.

You will be asked to continue with the study treatment for as long as your cancer does not get worse, as long as you do not have serious side effects or until the doctor or you consider that you need to withdraw for other reasons. You may continue to receive the study treatment(s) after your disease has progressed (due to so called radiological progression) if your study doctor considers it would be in your best interest.

If you have a serious side-effect during the study, the study doctor may hospitalize you, extend your hospital stay or ask you to visit the office for additional follow-up examinations, even after you have completed your regular study visits.

What will happen if I decide to take part in the study?

If you agree to take part in this research study, the study doctor will first need to conduct some “screening” tests and/or procedures on you and ask you some questions about your medical and cancer history and what medications you take, to ensure you are suitable for the study. Your demographic information, including your age, sex and race/ethnicity (if permitted) will be recorded.

Some of these tests or procedures may be part of your regular medical care and may be done even if you do not take part in this study.

The results of these screening assessments will determine whether or not you can take part in the study.

If the screening assessments show that you can be in the study, and you choose to take part, you will undergo further tests and procedures.

Assessments During Screening Visits:

- Discussion of the study, review and signing of this Informed Consent Form.
- Physical examination: The study doctor will conduct a full physical examination which will include your head, skin, eyes, ears, nose, throat, neck, lymph nodes, heart, lungs, abdomen, arms and legs, and nervous system. Your height and weight will also be measured.
- Medical/cancer history: The study doctor will ask you for detailed information about your medical history and the history of your {ovarian} {breast} cancer, including the cancer treatments you received. In addition, you will be asked about other medications (including all herbal/dietary supplements) taken within the last 30 days.
- Vital Signs: Your breathing rate, pulse, blood pressure and body temperature will be measured.
- Performance status (ECOG): You will be asked questions about your ability to perform daily activities.
- Electrocardiogram (ECG): An ECG is a test to measure how your heart is working by measuring the electrical activity (heart beat recording).
- Echocardiogram: An echocardiogram uses ultrasound to take images and videos of your heart and the blood flowing through your heart (heart imaging).
- Lung function test and Spirometry: These tests help your doctor understand how well your lungs are working. During this test, you will be asked to breathe deeply and exhale into a device for a few seconds.

- Blood collection: About 50 mL of blood will be taken for screening tests, which equates to about 3 tablespoons of blood. The samples will be used to:
  - Assess your general health by checking standard laboratory tests (including blood chemistry and blood counts), and tests to check how quickly your blood clots.
  - Test for viruses (HIV, hepatitis B and C).
  - To assess the function of your thyroid.
  - To test for tuberculosis.
  - Biomarker sample (for measuring a tumor marker, soluble CD25 (a soluble interleukin-2 receptor) in your body that help understand your disease and how the drug is affecting it).
  - Before your first dose a blood sample for genotyping will be collected (to look for genetic factors that may predict response to RO6870810. This sample can also be taken during the study treatment phase.)
- Urine samples: Collection of urine samples will be done to test for standard laboratory tests.
- Tumor imaging: A CT (computed tomography, a computerized series of X-rays) or MRI (magnetic resonance imaging, body pictures created using magnetic rather than X-ray energy) scan of chest, stomach area, pelvis and site of tumor will be done if no recent scans are available.
- Tumor biopsy: If available, a biopsy taken within the last three months may be used. If not available, a new tumor biopsy will be taken.
- Pregnancy Test (for women): A pregnancy test (if you can become pregnant) will also be conducted on your urine/blood sample.
- You should not receive vaccinations with live virus during the study (within 4 weeks prior to starting your study treatment) and within 5 months after the last infusion of atezolizumab.
- You will need to answer questions about how you are feeling, symptoms, behavior, and any changes to health, life and daily activities.

Imaging Techniques

- Tumor imaging: A CT (computed tomography, a computerized series of X-rays that image the internal organs and bones of your body using X-rays) or MRI (magnetic resonance imaging) scan of all your tumor sites will be done if no recent scans are available.

  You would likely undergo these scans even if you were not participating in this research study because your doctor would need to monitor your disease. These images are necessary in this study to measure your response to this treatment.

Depending on your specific condition, you may have one or more of the following types of scans:

- Computed Tomography (CT) scan of your chest, abdomen, and pelvis. This may include the administration of a contrast agent to be taken by mouth and/or injected to improve the ability to see your tumors (see section below on Use of Contrast Agents).
- Magnetic Resonance Imaging (MRI) scan of your whole body. An MRI scanner uses magnetic fields and radio waves rather than X-ray energy to image your body. If you have certain types of metal or implants in your body, you are not able to have an MRI scan.
- A chest X-ray will be done at Screening to check your lungs. This will only be necessary if the tumor scan cannot be used for this purpose.

Your study doctor will explain which type of imaging and the procedures that will be used.

Assessments during Study Treatment:

If the screening assessments show that you can be in the study, and you choose to take part, you will undergo the following tests and procedures:

- Weight measurement: Your weight will be measured throughout the study to make sure you continue to receive the dose assigned to you, even if your weight changes.
- Vital Signs: as described for Screening Procedures.
- Performance status (ECOG): as described for Screening Procedures.
- Electrocardiogram (ECG): as described for Screening Procedures.
- Blood collection: During the treatment period, blood samples will be taken, as follows:

  - Run-In period (Group 2 only): About 125 mL of blood (about 9 tablespoons).
  - Cycle 1: About 129 mL of blood (about 9 tablespoons).
  - Each of the following cycles: About 45-52 mL (about 3 tablespoons).
  - End of Treatment Visit: About 30 mL (about 2 tablespoons).

  The number of blood draws will be different on different days. The samples will be used for:

  - Standard laboratory tests (include blood chemistry and blood counts).
  - Tests to check how quickly your blood clots.
  - Biomarker samples (measuring markers in your body that help understand your disease and how the drug is affecting it).

  - Assessing the effect of the drug in your body.
  - For evaluating tumor-specific proteins, tumor markers, related to your type of cancer that may be circulating in your blood.
  - Measuring the amount of drug present in the blood (pharmacokinetics).
  - Determining if your body has developed proteins against the study drug atezolizumab, called anti-drug-antibodies (ADAs). These proteins would lower the amount of atezolizumab in your body (This will only be done for Group 2 participants if you receive atezolizumab after the Run-In period.)
- Urine collection: Urine samples will be taken for standard laboratory tests.
- Tumor imaging: You will undergo CT and/or MRI scans every 6 weeks (as described in the Screening section) in order to measure possible tumor response to study treatment.
- Tumor biopsy: For participants in Group 2, a tumor biopsy will be taken at the end of the Run-In period and at the end of the first treatment cycle. For participants in Groups 3 and 4, a tumor biopsy will be taken at the end of the first treatment cycle (prior to the start of Cycle 2). A tumor biopsy may also be collected at the time of disease progression, if decided by the Study Doctor.
- Pregnancy Test (for women): A pregnancy test (if you are able to become pregnant) will also be conducted on your urine/blood sample throughout the study.
- You will need to answer questions about how you are feeling, symptoms, behavior, and any changes to medicines, health, life and daily activities.

What will happen when I stop taking study drug?

You will be asked to come to the clinic for a safety and follow-up visit. It will be scheduled about 30 days after you have taken your last dose of RO6870810 and/or atezolizumab, depending on which study drug was taken last.

If your participation in the study is stopped earlier than planned, you will also have a visit at the time of withdrawal. This could be because you have had to stop treatment due to safety concerns, or because you or your study doctor determined it was in your best interest to stop participation.

The following procedures will be done at the safety and follow-up visit:

- Physical examination: as described for Screening Procedures.
- Vital Signs: as described for Screening Procedures.
- Blood collection: About 10-22 mL of blood will be taken, which equates to about 1.5 tablespoons of blood. These blood samples are for:
  - Standard laboratory tests (include blood chemistry and blood counts).
  - Tests to check how quickly your blood clots.

  - Measuring the amount of drug present in the blood (pharmacokinetics; end of treatment visit only).
  - To determine if your body has developed ADAs against atezolizumab (end of treatment visit only).
- Tumor biopsy: A tumor biopsy may also be collected at the time of disease progression/ end of treatment, if decided by the Study Doctor.
- Pregnancy Test: A pregnancy test (if you are able to become pregnant) will also be conducted on your urine/blood sample.
- You will need to answer questions about how you are feeling, symptoms, behavior, and any changes to medicines, health, life and daily activities.

Post-Treatment Follow-Up Assessments

Following the end of your participation in the study, your study doctor (or an appointed delegate) may contact you or your family or caregiver, or access your medical records or publically available records, to determine your long-term health status.

This long-term follow-up period will include a clinic visit or a telephone call once every 3 months for up to 1 year. You will need to answer questions about how you are feeling, symptoms, behavior, and any changes to medicines, health, life and daily activities.

If you decide you no longer want to be contacted or allow access to your medical records for follow-up information, tell your study doctor.

Biomarkers and Genetic Analysis in this study

Biomarkers are biological markers in the body that can be measured and used to explain how the body responds to a treatment for a particular disease. By looking at biomarkers in this study, Roche tries to understand why the course of your disease can be different in individual patients and if there is a way to tailor treatment to fit each patient's individual characteristics for treatment in the future. Examples of biomarkers are proteins found in blood, tumor tissue, or variations in a patient's individual genes (DNA).

New generation sequencing (NGS) or other genomic analysis may also be performed on tumor tissue samples. This is an analysis of your genetic material (DNA and RNA), that serves as an "instruction book" for the cells that make up your body. NGS data from large numbers of patients and healthy volunteers may help researchers learn how variations in the sequence of genes might affect a disease or a person's response to treatment, may identify possible links among diseases, and may provide new avenues for drug development and personalized therapies. Information from the NGS analysis will not be made available to you or to your doctor, unless required by law. Information from the testing will not be part of your medical record and will not be given to your insurance company or employer.

You may not benefit from the results of the biomarkers tested in this study since it may take several years for results to be available. However, it is possible that the treatment of future patients with your type of cancer can be improved based on the biomarkers that are evaluated in this study.

In this study, biomarker analyses will be conducted on blood and tumor tissue samples.

What will happen to my samples?

Samples collected for study-related analyses will be stored for up to 5 years after the study results have been reported:

- Blood samples collected for:
  - Biomarker samples (gaining additional knowledge that enhances the understanding of the disease and the drug).
  - Assessing the effect of the drug in your body.
  - Measuring the amount of drug present in the blood (pharmacokinetics).
  - Anti-drug antibodies (to determine if your body has developed antibodies to the study drug).
- Tumor tissue samples collected for genetic profiling.

Samples collected for clinical genotyping may be stored up to 2 years after the study results have been reported.

However, you may choose to donate your leftover samples for future research, as described in the last section of this Informed Consent Form (see "Consent for Optional Collection of Samples for the Research Biosample Repository").

If you withdraw from the study, any sample collected prior to your withdrawal may still be analyzed as described in the Informed Consent Form, unless you specifically ask for your samples to be destroyed or local laws require destruction of the samples.

Can I stop participating in the study?

Yes. You can decide to stop participating at any time. Tell the study doctor if you are thinking about stopping or decide to stop. The study doctor will tell you how to stop safely.

The Study Doctor may stop you from taking part in this study at any time, even if you want to continue, for reasons that include but are not limited to the following:

- Your safety would be at risk if you continued in the study.
- You failed to adequately follow instructions or procedures.
- You need a treatment that is not allowed by the study.

- The study has been cancelled.

When your participation ends, no new health information will be collected about you. However, Roche will still be able to use any health information about you that has already been collected during this study.

What are the possible risks or side-effects of being in the study?

You may have side-effects (also called adverse events) from the medications or procedures used in this study. However, Roche, the study doctor, and other doctors do not know all of the side-effects that could occur. Side-effects can vary from mild to very serious and may vary from person to person. Many side-effects go away soon after you stop what is causing them. In some cases, side-effects can be serious (in very rare cases may be fatal) and may be long-lasting or may never go away. You should talk to your study doctor about any side-effects you have while taking part in the study. Everyone taking part in the study will be watched carefully for any side-effects, and cared for as appropriate. Your study doctors may give you medications to help lessen side-effects.

The combination of RO6870810 and atezolizumab is experimental and has not yet been evaluated in humans. For this reason, the side-effects are not known at this time.

Allergic Reactions

Allergic reactions can occur with any drug and this can be in the form of itching, difficulty breathing, and a skin rash and/or drop in blood pressure. In very rare cases, you could suffer a life-threatening allergic reaction. If you do experience any such reaction, you should tell your study doctor immediately so that you can receive the appropriate treatment.

Side-Effects Known to be Associated or Potentially Associated with RO6870810

RO6870810 (administered alone) is currently being evaluated in two ongoing studies in humans, NP39141 and NP39142. Study NP39141 enrolled patients with solid tumors, nuclear protein in testis (NUT)-midline carcinoma and Diffuse Large B-Cell Lymphoma (DLBCL), while study NP39142 enrolled patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Approximately 80 patients have received RO6870810 within these two studies.

Based upon the clinical experience with RO6870810 in the two ongoing studies, side-effects known to be associated or potentially associated with RO6870810 administration are the following:

- Anemia (low number of red blood cells, which may make you feel more tired).

- Thrombocytopenia (low number of platelets, blood cells that help to stop bleeding).
- Abnormal laboratory tests, including abnormal results of liver function tests (elevation of blood aspartate aminotransferase [AST], alanine aminotransferase [ALT] and bilirubin levels).
- Fatigue (tiredness).
- Gastrointestinal disorders (nausea, vomiting, diarrhea, constipation, dry mouth).
- Decreased appetite.
- Dysgeusia (an alteration of the sense of taste).
- Injection site reactions (e.g., injection site erythema, pain, induration, pruritus, swelling, bruising or hemorrhage).

Very common side-effects (occurring in more than 10 out of 100 patients, or, in more than 10% of patients), reported in clinical trials with RO6870810, but not necessarily linked to RO6870810 treatment, are listed below:

- Febrile neutropenia (fever and a significant reduction in a type of white blood cells, known as neutrophils, which are needed to fight infections).
- Abdominal pain (or belly pain)
- Malaise
- Back pain
- Dyspnea (difficult or labored breathing)
- Hypomagnesemia (a decrease in magnesium levels in blood),
- Dehydration (a condition when your body does not have as much water and fluids as it should).
- Headache
- Myalgia (muscle pain)
- Cough
- Dizziness
- Epistaxis (bleeding from the nose)
- Pyrexia (fever)
- Asthenia (abnormal physical weakness or lack of energy)
- Insomnia
- Edema peripheral (accumulation of fluid causing swelling in tissues, usually in the lower limbs)
- Petechiae (a small red or purple spot caused by bleeding into the skin)
- Angina bullosa haemorrhagica (sudden appearance of one or more blood blisters within the oral cavity)
- Cardio-respiratory arrest (none attributed to RO6870810 treatment)

- Hypoxia (deficiency in the amount of oxygen reaching the tissues)
- Pain in extremity
- Pneumonia
- Weight loss
- Ecchymosis
- Oropharyngeal pain
- Transfusion reaction

These side-effects are considered to be acceptable and manageable. In addition, no side-effects resulting in death have been attributed to RO6870810 treatment.

Based on tests in animals at doses higher than those that will be used in this study, there may be additional side-effects from RO6870810, which may include the following:

- Prolongation of the QT-interval on electrocardiograms (a disorder of the heart that can cause serious irregular heart rhythms which may lead to fainting, heart attack or death).
- Pericarditis (inflammation of the outer layer of the heart that can cause chest pain).
- Lung inflammation.

To date, neither events of irregular heart rhythm nor inflammation of the heart or lung have been reported as side-effects in humans treated with RO6870810.

You should not take RO6870810 if you previously had a serious allergic reaction to any other drug that, in the opinion of the Investigator, poses an increased risk to you.

Side-Effects Known or Suspected to be Associated with Atezolizumab

Atezolizumab is designed to increase the number of immune system cells in your body that can fight cancer. These cells may cause inflammation within the tumor, as well as in normal tissue (immune-related side-effects). Therefore, by taking atezolizumab, you may develop a condition where there is inflammation against a part of your own body (an autoimmune condition).

The side-effects described in this section are known to be associated with atezolizumab and are based on pooled data from completed and ongoing studies with atezolizumab

and the atezolizumab safety database.

Side-Effects Known to Be Associated with Atezolizumab		
Common (occurs in more than 10% of patients)	• Fatigue • Joint pain (arthralgia) • Lack of energy (asthenia) • Decreased appetite • Diarrhea • Shortness of breath (dyspnea) • Stomach area pain (abdominal pain)	• Headache • Itching of the skin • Nausea • Fever • Rash • Vomiting • Muscle and bone pain (myalgia, musculoskeletal pain and bone pain)
Less common (occurs in 1%–10% of patients)	• Chills • Difficulty swallowing (dysphagia) • Increase in liver enzymes, which may indicate inflammation of the liver • High levels of sugar in the blood (hyperglycemia) • Allergic reaction or intolerance to medication (hypersensitivity) • Decreased level of potassium in blood (hypokalemia) • Decreased level of sodium in blood (hyponatremia) • Low blood pressure (hypotension) • Underactive thyroid gland (hypothyroidism)	• Inflammation of the intestines (colitis) • Decreased oxygen supply in body resulting in shortness of breath (hypoxia) • Flu-like symptoms • Infusion-related reaction • Muscular weakness • Nerve damage resulting in possible numbness, pain, and/or loss of motor function (peripheral neuropathy) • Inflammation of the lungs (pneumonitis) • Low platelet count in the blood, which may make you more likely to bruise or bleed (thrombocytopenia)
Rare but potentially serious (occurs in less than 1% of patients)	• Decreased production of hormones by the adrenal glands (adrenal insufficiency) • Diabetes • Overactive thyroid gland (hyperthyroidism) • Inflammation of the liver (hepatitis) • Inflammation of the brain and membrane surrounding the brain and spinal cord (meningoencephalitis) • Inflammation of the pituitary gland (hypophysitis) • Inflammation of the heart muscle (myocarditis) • Inflammation of the kidneys (nephritis)	• Nerve damage that may cause muscle weakness and/or paralysis (Guillain-Barré syndrome) • Nerve damage resulting in muscle weakness (myasthenic syndrome/myasthenia gravis) • Inflammation of the pancreas (pancreatitis) • Increase in pancreatic enzymes, which may indicate inflammation of the pancreas (increase in amylase and lipase) • Severe high levels of sugar and acids in the blood or urine (diabetic ketoacidosis) • Abnormal renal function tests which may indicate inflammation of the kidneys (Increase in creatinine)

SYMPTOMS ASSOCIATED WITH ATEZOLIZUMAB SIDE-EFFECTS

Among the side-effects known to be associated with atezolizumab, Roche and your study doctors would like you to pay more attention to the following:

- Inflammation of the intestines (colitis); symptoms may include diarrhea, blood in stool, and pain in stomach area.
- Inflammation of the thyroid glands (hypothyroidism, hyperthyroidism); symptoms may include headaches, fatigue, weight loss, weight gain, change in mood, hair loss, and constipation.
- Inflammation of the adrenal glands (adrenal insufficiency); symptoms may include dizziness, irritability, fainting, low blood pressure, skin darkening, and craving of salty foods.
- Inflammation of the pituitary gland (hypophysitis); symptoms may include fatigue and headaches that will not go away, increased thirst, increased urination, and changes in vision.

  Side-effects that may occur at the same time include hypothyroidism and adrenal insufficiency (see above for details).
- Inflammation of the liver (hepatitis); symptoms may include yellowing of skin, pain in stomach area, nausea, vomiting, itching, fatigue, bleeding or bruising under the skin, and dark urine.
- Inflammation of the brain and membrane surrounding the brain and spinal cord (meningoencephalitis); symptoms may include neck stiffness, headache, fever, chills, vomiting, seizure, irritability, and eye sensitivity to light.
- Nerve damage resulting in muscle weakness (myasthenic syndrome/myasthenia gravis); symptoms may include weakness in the arm and leg muscles, double vision, and difficulties with speech and chewing.
- Nerve damage that may cause muscle weakness and/or paralysis (Guillain-Barré syndrome); symptoms may include tingling in fingers and toes, fatigue, and difficulty walking.
- Inflammation of the lungs (pneumonitis); symptoms may include new or worsening cough, shortness of breath, and chest pain.
- Inflammation of the heart muscle (myocarditis); symptoms may include shortness of breath, decreased exercise tolerance, fatigue, chest pain, swelling of the ankles or legs, irregular heartbeat, and fainting.
- Reactions associated with infusion (events occurring during or within 1 day of infusion); symptoms may include fever, chills, shortness of breath, and sudden reddening of the face, neck, or chest.
- Inflammation of the pancreas (pancreatitis); symptoms may include abdominal pain, nausea, vomiting, and fever.
- Condition of high levels of sugar in the blood (diabetes mellitus); symptoms may include increased thirst, increased hunger, frequent urination, irritability, and fatigue.

- Inflammation of the kidneys (nephritis); symptoms may include changes in urine output and color, pain in pelvis, and swelling of the body, and may lead to failure of the kidneys.

ALLERGIC REACTIONS WITH ATEZOLIZUMAB

Allergic reactions may occur with atezolizumab and typically occur while it is being administered into your vein or shortly after it has been administered. Symptoms could include nausea, vomiting, skin reactions (hives or rash), difficulty breathing, or low blood pressure. These reactions could be mild or severe and might lead to death or permanent disability. If you experience any of these symptoms, your study doctor will interrupt, or even stop, the delivery of atezolizumab into your vein. Your study doctor may also give you some drugs to treat these symptoms.

You should not take atezolizumab if you previously had a serious allergic reaction to any other drug that, in the opinion of the Investigator, poses an increased risk to you.

SIDE-EFFECTS POTENTIALLY ASSOCIATED WITH ATEZOLIZUMAB

POTENTIAL SIDE-EFFECTS WITH ATEZOLIZUMAB

The following are side-effects that may be associated with atezolizumab:

- When you receive atezolizumab, there is a possibility that your immune system might make ADAs. It is possible that this may occur after the administration of monoclonal therapeutic antibodies in general. If you develop these particular antibodies, it may affect your body's ability to respond to atezolizumab and other drugs of a similar type. You will be monitored for such antibodies during the course of the study. At times, side-effects can occur due to the development of ADAs, which worsen over time (also called hypersensitivity reaction). Usually, these side-effects are skin rash, joint and muscle pain, fever, and tiredness. Your study doctor can prescribe medications to decrease the effect of these symptoms. If these side-effects are severe or persist for a very long time, it may be necessary to permanently discontinue the administration of atezolizumab.
- Potential harm to a developing fetus.
- Inflammation of the eye (uveitis); symptoms may include eye pain and redness, vision problems, or blurry vision.
- Inflammation or damage of the muscles; symptoms may include muscle pain and weakness, urine with a dark brown or reddish color, and nausea or vomiting. This may include muscle inflammation (myositis), muscle disease (myopathies) and muscle injury that may cause further complications such as kidney failure (rhabdomyolysis).
- Inflammation of the blood vessels that can lead to damage of different organs (vasculitis); symptoms may include fever, fatigue, weight loss, weakness, general aches and pains, rash, headache, lightheadedness, shortness of breath, and numbness.

- Breakdown of red blood cells (autoimmune hemolytic anemia); symptoms may include fatigue, fever, lightheadedness, paleness of the skin, yellowing of the skin and/or eyes, weakness, and inability to do physical activity.
- Severe skin or mucosal reactions (severe cutaneous adverse reactions); symptoms may include severe skin or mucosal blistering, shedding, scaling, and death of the skin or mucosa.

SYSTEMIC IMMUNE ACTIVATION

- In rare situations, when atezolizumab is combined with another drug that also increases your body's immune response (immune-modulating drugs), a more-than-normal (excessive) immune response can occur. Like other immune-mediated conditions, excessive systemic immune activation can cause side-effects related to severe inflammation and or generalized infection (sepsis). Several organs in your body (for example liver, kidney, lungs, and bone marrow) may become involved, causing a serious condition, which could lead to hospitalization, life-threatening circumstances, or even death. Symptoms of systemic immune activation may include very low blood pressure that does not respond to standard treatment including fluids given through the veins (intravenous fluids), high-grade fever (more than 38.5° Celsius), cough, severe shortness of breath (respiratory distress) requiring oxygen therapy and/or mechanical help (intubation), severe dizziness, confusion, weakness, decreased urination with failure of the kidneys (renal failure), significantly high levels of liver enzymes (liver failure), very low blood cell counts, and/or bleeding within the organs.
- If you experience any of these symptoms, you should notify your doctor immediately as you may need immediate treatment and hospitalization. Your study doctor may give you drugs to treat these symptoms.

Risks Associated with Drug Administration

Both of the study drugs will be administered through a needle that will be placed in your arm. You may experience mild discomfort during the procedure, and there is a small chance of infection by placing the needle in your arm, but every medical precaution will be taken to avoid an infection.

Risks Associated with Study Procedures

Blood Sampling

During this study, small amounts of blood will be drawn from a vein and used for tests that allow your study doctors to see how you are doing. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising or infection at the place where the needle is inserted. Very rarely, a blockage of the vein or a small nerve injury can occur, resulting in numbness and pain. However, this will resolve with time. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

On days when several blood samples will be taken, we may use a cannula (small plastic tube) inserted in your arm using a small needle. This cannula may remain in place for

the day and will be taken out before you go to bed at night. There is a small chance of infection by placing the cannula in your arm, but every medical precaution will be taken to avoid an infection.

Electrocardiogram (ECG)

You will have small, soft pads, placed stuck temporarily on different parts of your body. There is no pain or discomfort during an ECG; however, the area of skin in which the ECG pads will be stuck may need to be shaved, and the pads may cause a skin reaction such as redness or itching. Taking the pads off may cause localized irritation to the skin and/or hair loss, similar to having a plaster taken off.

Biopsies

You may feel some amount of pain or discomfort during the biopsy, including slight stinging pain when a local anesthetic is injected by needle to numb the area, pressure and dull pain where the biopsy needle is inserted, discomfort from lying still for an extended time, and soreness at the biopsy site. If a general anesthetic is used, you will not feel pain during the procedure because you will be asleep. Your doctor will explain the risks of the biopsy procedure to you.

In patients who undergo a lung biopsy, the risks also include lung collapse.

CT Scans

You will be exposed to radiation from CT scans approximately every 6 weeks. During each tumor assessment, the total radiation dose to your whole body will be about 21 millisieverts (mSv; a measurement of radiation received. People are exposed to radioactivity [from rocks, cosmic rays and other sources] at all times. It is called “background” radiation and cannot be avoided. There is no evidence that these differences in background radiation lead to any obvious health risks), which is 40% of the 50-mSv annual whole-body limit for adult radiation workers (i.e., the amount of radiation that is not expected to be harmful over an one-year period). Since the effects of radiation can build up over time, it is important to know of your past radiation exposure. If you have been exposed to radiation through CT scans, X-rays, or other means in the past 12 months, please inform study personnel. If it is determined that your prior radiation exposure exceeds current guidelines, it is possible that you will not be allowed to participate in this study.

As part of the CT scan, a contrast agent may need to be taken by mouth and/or injected into your vein to make certain organs and disease sites visible on the scan. Please see section below for risks associated with contrast dye for CT/MRI scans.

CT scanners are quite ‘closed in’ and may be unpleasant for people who have a fear or strong dislike of enclosed spaces. Staff at the imaging center use techniques to help

reduce these feelings and your study doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms.

MRI Scans

For most participants, the risks or side-effects associated with undergoing MRI are very minimal.

MRI scanners are quite 'closed in' and may be unpleasant for people who have a fear or strong dislike of enclosed spaces. Staff at the imaging center use techniques to help reduce these feelings and your study doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms. Because an MRI scanner uses strong magnets, you cannot have any metal implants in your body to have an MRI scan. People with an artificial heart valve, metal plate, pin, or other metallic objects in their body (including gun shot or shrapnel) will not be eligible for this study. If you have any tattoos, you might feel a little discomfort when you have your MRI scan, and if you use a hormone replacement therapy (HRT) patch, you'll have to take it off during the MRI scan, because it might cause discomfort during the scan. Study personnel will ask you questions to make sure you can safely have an MRI scan.

Use of Contrast Agents

The risks associated with oral contrast agents used for CT scans may cause side-effects such as nausea, constipation, diarrhea, and abdominal bloating. Pain, bruising, redness, swelling, or infection may occur at the site where a needle is inserted to administer the contrast material into your vein. It is normal to experience a warm, flushing feeling when the contrast material is given. You may have an allergic reaction (see previous section).

As part of the standard MRI scan, a contrast agent containing gadolinium is injected into your vein to enhance visibility and improve the images taken. The risks associated with the contrast agent include mild nausea, headache, hives, temporary low blood pressure, chest pain, back pain, fever, weakness, and seizures. There have been reports of a severe and potentially fatal condition known as nephrogenic systemic fibrosis (a scarring condition that can lead to kidney failure) that has occurred in some patients who received gadolinium-based contrast agents. This has not been seen in patients with normal working kidneys or mild problems in kidney function. Prior to study entry, your study doctor will run routine tests to determine if your kidneys are working properly to make sure that the contrast agent is safe for you.

As all contrast agents may worsen kidney function in people who already have kidney disease or who are dehydrated (have not had enough liquids that day), your study doctor will monitor your kidney function closely while you participate in this study. Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast dye.

Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare, but can be severe and life-threatening.

Reproductive Risks

Reproductive Risks for Women

If you are pregnant or become pregnant, or if you are currently breastfeeding, you cannot take part in this study because you or your child may be exposed to an unknown risk.

If you are a woman who can become pregnant, you must have a test that shows you are not pregnant before you can be enrolled in this study. You may also have further pregnancy tests during the course of the study. If the urine test is positive, a repeat (blood) pregnancy test will be taken to confirm the result. If the blood test is positive, you will not receive any more study medication.

If you can become pregnant, you must agree to use remain abstinent or use birth control methods that are judged to be effective by your study doctor during this study and for 2 months after your last dose of RO6870810 or for 5 months after the last dose of atezolizumab. Check with your study doctor about the methods of birth control to use.

Tell your study doctor right away if you suspect that you have become pregnant during the study or within 2 months after your last dose of RO6870810, or within 5 months after the last dose of atezolizumab. The study doctor or research staff will advise you of the possible risks to your unborn child and the options available to you. In addition, the study doctor will want to follow up with you until the outcome of the pregnancy is known.

Reproductive Risks for Men

If your partner is able to become pregnant, you must agree to remain abstinent or use a condom plus additional birth control methods that are judged to be effective by your study doctor during this study and for at least 4 months after your last dose of RO6870810 to avoid exposing your child to an unknown risk. Check with your study doctor about the methods of birth control to use. If your partner is pregnant, you must remain abstinent or use condoms for at least 4 months after your last dose of RO6870810.

You should not donate sperm during this study and for at least 4 months after your last dose of RO6870810.

Tell your study doctor right away if your partner becomes pregnant during the study or within 4 months after your last dose of RO6870810. The study doctor or research staff will advise you of the possible risks to your unborn child and will make an effort to contact your partner to get her permission to collect information about the pregnancy. No matter what your partner decides, you can continue to take part in this study.

Possible Risks Associated With Loss Of Privacy

Although your genetic information will not contain any personal identifying information, there is a very small risk that it could be linked to an outside public database and used to help identify you and your blood relatives. Because some genetic differences can help to predict future health problems experienced by you or your blood relatives, this information might be of interest to health care providers, life insurance companies, and others. It is possible that your genetic information could be used in ways that would cause you or your family distress, such as by revealing that you or a blood relative carries a genetic disease. Your privacy is very important, and Roche uses many safeguards to protect your privacy. However, there is no guarantee that your identity will never become known. Refer to the "Will my medical and personal information be kept private?" section for information about laws that protect against certain genetic discrimination.

Are there benefits to taking part in the study?

There is no guarantee that you will receive any benefits from this study, and taking part in this study may or may not cause your health to improve. Information from this study may help doctors learn more about RO6870810 in combination with atezolizumab and the treatment of {ovarian} {breast} cancer. This information may benefit other patients with {ovarian} {breast} cancer or a similar condition in the future.

Will I continue to receive the study drug after the study is over?

You will be eligible to receive the study drug RO6870810 and/or atezolizumab free of charge after you complete the study if all of the following conditions are met:

- You have a life-threatening or severe medical condition and require continued study drug treatment for your well-being.
- There are no appropriate alternative treatments available to you.
- You and your doctor comply with and satisfy any legal or regulatory requirements that apply to you.

You will not be eligible to receive the study drug after you complete the study if any of the following conditions are met:

- The study drug is commercially marketed in your country and is reasonably accessible to you (e.g., is covered by your insurance or wouldn't otherwise create a financial hardship for you).
- Roche has discontinued development of the study drug or data suggest that the study drug is not effective for {ovarian} or {breast} cancer.
- Roche has reasonable safety concerns regarding the study drug as treatment for {ovarian} or {breast} cancer.

- Continued access to study drug is not permitted under the laws and regulations of your country.

Will I be told about new information?

During the study, you will be told in a timely manner about new information or changes in the study that may affect your health or your willingness to continue in the study.

When informed of this new information, if you agree to continue in the study, you or your legally authorized representative will be asked to sign an updated consent form.

When informed of this new information, if you agree to continue in the study, you will be asked to sign an updated consent form.

What other choices do I have if I do not take part in this study?

Your other choices may include the following:

- Getting treatment or care for your {ovarian} or {breast} cancer without being in a study
- Taking part in another study
- Getting no treatment
- Getting comfort care (also called palliative care) only. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly.

Talk to your doctor about your choices, including the risks and benefits of each choice, before you decide if you will take part in this study.

Will I be reimbursed if I take part in this study?

Option 1: You will not be paid for taking part in this study.

Option 2: You will be reimbursed for your reasonable costs (e.g., transportation, parking) to travel from your home to {Study Site} for your study visits.

Information from this study may lead to discoveries and inventions or development of a commercial product. The rights to these will belong to Roche. You and your family will not receive any financial benefits or compensation from or have rights in any developments, inventions, or other discoveries that might come from this information.

Will it cost me anything to be in this study?

You will not be charged for RO6870810 or atezolizumab while you are participating in this study.

Also, all procedures that are required only for this study, and that are not part of your regular medical care, will be provided to you at no charge. {Responsible party [e.g., "You or your health plan"]} will need to pay for medicines and clinic, hospital, and doctors' services that are part of your regular medical care.***{Delete the following for sites not requiring this language:}*** Some health plans will not pay these costs for people taking part in research studies. Your study doctor can check with your health plan to find out what they will pay for.

After your participation in the study ends, {responsible party [e.g., "you or your health plan"]} will need to pay for medicines and clinic, hospital, and doctors' services that are part of your regular medical care.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. {Name}, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or her at {telephone number}.

You will get medical treatment if you are injured as a result of taking part in this study. Your study doctor will explain the treatment options to you and tell you where you can get treatment. ***{Delete the following for sites not requiring this language:}*** You and/or your health plan will be charged for this treatment.

{For U.S. sites, include the following:} Neither Roche nor the study doctor will pay for this medical treatment, and you will not receive any other kind of payment.

{Enter the country-specific wording for this section. The following language is acceptable patient injury language:}

Roche will pay for the reasonable costs of immediate care for any physical injury to you that specifically results from the study medication, but only if:

- Roche and the study doctor agree that your injury resulted from the study drug medication and not from a preexisting medical condition.
- The costs are not paid for by your medical insurance.
- Your injury did not result from a failure to follow study protocol or instructions, or from the negligence, mistakes, or misconduct of the study personnel.

You will not receive any other kind of payment.

{Include the following for ex-U.S. countries that require a statement about research insurance:} You should submit your request for financial compensation for treatment costs to Dr. {Name}, who will make sure that Roche takes appropriate action. To ensure that Roche can settle claims for financial compensation, Roche maintains a contract with {Insurance Company}.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose to either take part or not take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Will my medical and personal information be kept private?

Protection, Use and Sharing of Information

During this study, health and personal information ("information") about you will be collected. This section describes the protection, use, and sharing of your information, which consists of the following:

- Information in your medical record, which is held by {Study Site}
- Information that is collected or produced during this study ("study data"), which is held by {Study Site}, Roche, Roche affiliates, and Roche's representatives (people and companies who work for Roche)

Your privacy is very important, and Roche uses many safeguards to protect your privacy, in accordance with applicable data privacy laws and laws related to the conduct of clinical trials.

Your study data and samples will be labeled with a patient identification (ID) number that is unique to you and not related to or derived from information that identifies you (such as your name, your picture, or any other personally identifying information). Roche, Roche affiliates, and Roche's representatives will only have access to study data and samples labeled with a patient ID number, except as described below. Your medical record, which includes personal information that can identify you, will not be accessed for the purposes of this study, except as described below:

Your information (which includes information in your medical record that can identify you) may need to be reviewed to make sure the study is being done properly or to check the quality of the information. This information will be kept private. The following people and groups of people may review ***{If copying of information is not allowed, delete "and/or copy":}***and/or copy this information:

- Study monitors of Roche and/or {name of CRO}, a company hired by Roche to perform certain study activities
- The Institutional Review Board or Ethics Committee responsible for protecting the rights and safety of the participants who take part in research studies

- Regulatory authorities (government agencies involved in keeping research safe for people)

Study data, which may include genetic data, may be submitted to government or other health research databases or shared with researchers, government agencies, companies, or other groups that are not participating in this study. These data may be combined with or linked to other data and used for research purposes, to advance science and public health, or for analysis, development, and commercialization of products to treat and diagnose disease. These data will not include information that identifies you, and extra steps will be taken to safeguard your privacy.

Your information will not be given to your insurance company or employer, unless required by law. If the results from this study are published in a medical journal or presented at a scientific meeting, you will not be identified.

Information from this study will be retained by {Study Site} for {retention period [e.g., 15 years after the end of the study]}. In addition, Roche will retain the study data for up to 25 years after the end of the study.

is collecting samples for genetic testing (i.e., analysis of DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes):

{For U.S. sites, include the following:}

A federal law, called the Genetic Information Nondiscrimination Act, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that Roche obtains from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that Roche obtains from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

{For ex-U.S. sites, insert information about country-specific genetic discrimination law, if applicable:}

{Text}

Study Results

A clinical study report containing the results of this trial will be made available to anyone who requests a copy. However similarly, it would not be possible for the reader to identify you personally from any of the information contained within it.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If information from this study is published in a medical journal or presented at scientific meetings, you will not be identified by name, picture, or any other personally identifying information.

How will health information that identifies me be used and disclosed?

{For ex-U.S. sites, include the following:}

If you sign this consent form, you give permission to {Study Site} to use and/or disclose (share) your information that identifies you only for the purposes of this study and for research directly related to ovarian or breast cancer, the use of RO6870810 in disease therapy, and/or the development of tests that help with detection or understanding of your disease. You do not have to sign this consent form, however if you (or your representative) do not sign the consent form, you cannot take part in this study.

The information for which you are giving permission to be used and/or shared includes study data and information that is in your medical records.

Your study data may be used by and/or shared with Roche, Roche affiliates, Roche's representatives, collaborators, and licensees, the Institutional Review Board or Ethics Committee, and regulatory authorities. Your study data may be analyzed in any country worldwide. Such countries may have less data protection safeguards and rights than the country where your study site is located.

{For ex-U.S. sites located in the European Economic Area, also include the following:}

Transfer of your study data to Roche affiliates and Roche's representatives, collaborators, and licensees who are located outside of the European Economic Area is protected adequately under separate agreements such as "Standard Data Protection Clauses."

You have the right to see and get a copy of your study data. However, by signing this consent form, you agree that you generally will not be able to review or receive some of your records related to the study until after the entire study has been completed. This is to protect the scientific integrity of the study. If you believe any of the personal data

(i.e., information that identifies you or could reasonably be used to identify you) in these records to be inaccurate or incomplete, you have the right to request its correction. You can request the deletion of any personal data that are no longer needed. You can also request the restriction of the use of any personal data. Because Roche only maintains study data labeled with your patient ID number, Roche may not be able to fully respond to your request. Roche will try to be as responsive as possible to your requests, taking into consideration the impact on the scientific integrity of the study. To request a copy of your study data, request that your personal data be corrected or deleted, or request the restriction of the use of your personal data, contact your study doctor (see Section 2.8), who will forward your request to Roche.

You may change your mind and take back your consent at any time without penalty or loss of any benefits to which you are otherwise entitled. If you take back your consent, you will not be able to continue to take part in the study and no new information will be collected about you. However, to comply with regulatory requirements to protect the scientific integrity of the study, Roche will still be able to use and share any study data about you that have already been collected during this study. To take back your consent, you may contact your study doctor (see Section 2.8).

If you have any questions, concerns, or complaints as to how Roche is using your information, you can contact Roche's local Data Protection Officer at {contact information [e.g., name and email address], located at https://finance-mdms.roche.com/ds/cfgappl.rca (select "Finance MDMS" → "Roche Corporate Addresses" → "Key Persons" → "Data Protection Officer" Role → "Run Report")}. For more information about your privacy rights or if you are not able to resolve a problem directly with Roche and wish to make a complaint, you may contact {Name of data protection authority} ({contact information [e.g., email address]}), which is responsible for making sure that privacy law is followed in {Country}.

{If local applicable law requires more stringent data protection measures, insert such additional country-specific data protection language:}

{Text}

{For U.S. sites providing a separate HIPAA authorization, include the following:}

You will be asked to sign a separate authorization form that gives {Study Site} permission to use or disclose (share) your health information that identifies you only for the purposes of this research study and for research directly related to ovarian or breast cancer, the use of RO6870810 in disease therapy, and/or the development of tests that help with detection or understanding of your disease (see the separate authorization form for more details).

{For U.S. sites NOT providing a separate HIPAA authorization, include the following:}

If you sign this consent form, you give permission to {Study Site} to use or disclose (share) your health information that identifies you only for the purposes of this research study and for research directly related to ovarian or breast cancer, the use of RO6870810 in disease therapy, and/or the development of tests that help with detection or understanding of your disease. You do not have to sign this consent form, but if you do not, you may not take part in this research study.

The health information for which you are giving permission to be used and shared includes all health information about you that has been and will be created or received by {Study Site} and that is in your medical records kept by {Study Site}.

This health information that identifies you may be used by and/or disclosed to Roche, Roche affiliates, Roche's representatives, collaborators, and licensees, the Institutional Review Board or Ethics Committee, and regulatory authorities. Your health information and data may be analyzed in any country worldwide. Those persons who receive your health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws that apply to them.

You have the right to see and get a copy of your medical records kept by {Study Site} that are related to the study. However, by signing this consent form, you agree that you generally will not be able to review or receive some of your records related to the study until after the entire study has been completed, to protect the scientific integrity of the study.

Your authorization (permission) to use and disclose (share) your health information does not have an expiration date, but that use and sharing will only be for the purposes described in this consent form.

You are free at any time to limit {Study Site}'s use and sharing of your health information, without penalty or other consequence. However, you may not be allowed to take part or continue to take part in this research study if at any time you choose to limit {Study Site}'s use and sharing of your health information that is necessary for the completion of this research study.

You may change your mind and revoke (take back) this authorization at any time. If you revoke this authorization, no new health information will be collected about you. However, Roche will still be able to use and disclose any health information about you that has already been collected during this research study. To revoke this authorization, you must do so in writing by contacting your study doctor (see contact information in next section).

Include the following if the study requires testing for reportable diseases PT only:

{Delete the following for sites not requiring this language:} {Disease name } may be a reportable disease where you live. If you test positive for this disease, the law may mandate that your study doctor disclose your identity to the appropriate authority. Please ask your study doctor for details if you have concerns about this.

{For all U.S. sites, include the following:}

If a patient is eligible for Medicare, federal law requires Roche to inform the Centers for Medicare & Medicaid Services (CMS, the agency responsible for administration of the Medicare program) when Roche is going to reimburse for patient injury expenses for treatment of an injury to a Medicare beneficiary. To comply with a Medicare reporting obligation, Roche or its representative may need to collect and share with CMS certain personal information about you, such as your name, date of birth, sex, social security number, and Medicare ID number (if you have one).

Who can answer my questions about the study?

You can talk to your study doctor if you have any questions or concerns about this study, if you would like to withdraw your consent to take part in this study, or if you think you have been injured as a result of taking part in the study. Contact your study doctor, Dr. {Name}, at {address, telephone number}.

{For ex-U.S. sites, include the following if applicable:}You will receive a card indicating that you are participating in this study. The card will include the name and phone number of the study doctor. Please have this card with you at all times, as long as you remain in the study.

For questions about your rights while taking part in this study, call {Study Site}'s Institutional Review Board or Ethics Committee (a group of people who review the research to protect your rights) at {telephone number}.

If at any time during this study you feel that you have not been informed enough about your privacy rights about your health information, or you feel that the privacy of your health information has not been protected, you may contact {Contact Person/Organization} at {address, telephone number}.

Signature

I understand that I will be given a copy of all {total number of pages} pages of this form after it has been signed and dated. I have read it, or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this research study as described above and authorize {Study Site} to use and disclose (share) my information as described in this Informed Consent Form.

Patient name (print)	
If applicable – Name of patient's legally authorized representative (print)	Relationship to patient
Patient signature or signature of patient's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the patient named above and/or the patient's legally authorized representative.

Name of person conducting informed consent discussion (print)	
Signature of person conducting informed consent discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

[a] If the Principal Investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9).

CONSENT FOR OPTIONAL COLLECTION OF SAMPLES FOR THE RESEARCH BIOSAMPLE REPOSITORY

Introduction

Roche wants to better understand why certain patients are more likely to respond to treatment than others, to facilitate the development of personalized medicines—to get the right medicine to the right patient. Roche would like to use any leftover (unused) blood from biomarker samples, and tissue samples that were collected during the study, including any additional samples your doctor decided to collect during the study.

If you agree to donate samples for research, they will be stored in the Research Biosample Repository (RBR), a place where human samples are securely stored. Your samples will be stored in the RBR

{If the site does not require a defined storage period, include the following:} If you agree to donate samples for research, they will be stored in the Research Biosample Repository (RBR), a place where human samples are securely stored. Your samples will be stored in the RBR until they are no longer needed or until they are used up.

{If the site requires a defined storage period, include the following:}If you agree to donate samples for research, they will be stored in the Research Biosample Repository (RBR), a place where human samples are securely stored. Your samples will be stored in the RBR for up to {XX} years after the final study results have been reported.

Donating your samples to the RBR is entirely voluntary. No matter what you decide, it will not affect your participation in the main study or your medical care.

Why are these samples being collected and stored?

The samples in the RBR may be used to help researchers to:

- Better understand why certain people are more likely to respond to medicines than others.
- Better understand how and why diseases act differently in different people.
- Develop new treatments for diseases or medical conditions.
- Find reasons why certain people are more likely to have side-effects to medicines than others.
- Find out how medicines are processed by people's bodies and how such treatment may affect people's bodies.
- Develop better ways for preventing diseases or treating diseases earlier.
- Develop or improve tests that help with detection or understanding of diseases, to help identify the right medicine for the right patient.

- Analyze your genomic material to allow for exploration of broad health research questions across disease areas.

  Your genomic material (DNA and RNA) serves as an "instruction book" for the cells that make up your body. Your samples may be used for analysis of all of your DNA through whole genome sequencing (WGS), analysis of portions of your DNA that code for proteins, or research on gene interactions. Analyses of samples collected from a large number of patients and healthy volunteers may help researchers identify possible links among diseases, learn how variations in the sequence of genes might affect a disease or a person's response to treatment, and discover new avenues for drug development and personalized therapies.

- {Text }

What will happen if I agree to participate?

If you agree to participate in the RBR, samples will be collected as described below:

- Leftover blood, and tissue samples will be sent to the RBR, and you will not have to undergo an additional procedure.

What are the possible side-effects or risks?

POSSIBLE RISKS ASSOCIATED WITH SAMPLE COLLECTION

Risks associated with participating in the RBR are described below:

- There are no additional risks associated with donating your leftover blood and tissue samples to the RBR.

POSSIBLE RISKS ASSOCIATED WITH LOSS OF PRIVACY

Although your genetic information will not contain any personal identifying information, there is a very small risk that it could be linked to an outside public database and used to help identify you and your blood relatives. Because some genetic differences can help to predict future health problems experienced by you or your blood relatives, this information might be of interest to health care providers, life insurance companies, and others. It is possible that your genetic information could be used in ways that would cause you or your family distress, such as by revealing that you or a blood relative carries a genetic disease. Your privacy is very important, and Roche uses many safeguards to protect your privacy. However, there is no guarantee that your identity will never become known.

Are there benefits to donating samples?

You will not receive any direct benefit from donating your samples. However, research performed on these samples may benefit other patients with {ovarian} {breast} cancer or a similar condition in the future.

Will I be paid if I donate samples?

You will not be paid for donating samples to the RBR.

Information from this research may lead to discoveries and inventions or development of a commercial product. The rights to these will belong to Roche. You and your family will not receive any financial benefits or compensation from, nor have rights in any developments, inventions, or other discoveries that might come from, this information.

How will my privacy be protected?

To ensure that your health information is kept confidential, the forms, records, and samples that are maintained by Roche for the RBR will be labeled with your patient identification number; they will not be labeled with your name, picture, or any other personally identifying information. The samples and your health information will be kept under the same level of privacy as described above for the main study. Roche, people and companies who partner with Roche, and others acting on behalf of Roche may study the RBR samples and associated research data in any country worldwide. Roche may then send the research results to health authorities worldwide. Information from this research may be published in a medical journal or presented at scientific meetings, so that other doctors can find out about the results. Your identity will not be disclosed.

Information from the sample analyses will not be shared with you or your doctor, unless required by law. Information from the analyses will not be part of your medical record and will not be given to your insurance company or employer.

Your genetic research data may be shared with researchers who are not participating in this study or submitted to government or other health research databases for broad sharing with other researchers. You will not be identified by name or any other personally identifying information.

{For U.S. sites, include the following:}

A federal law, called the Genetic Information Nondiscrimination Act, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that Roche obtains from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that Roche obtains from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

{For ex-U.S. sites, insert information about country-specific genetic discrimination law, if applicable:}

{Text}

Can I change my mind about storing my samples in the RBR?

Yes. You can change your mind at any time. If you want to withdraw your consent for the use of your samples during the study, tell your study doctor that you no longer want your samples stored or used for research. If you want to withdraw your consent after the close of the study, follow the instructions provided to you by the study doctor. After you withdraw consent, any samples that remain will be destroyed or, if this is not technically possible (e.g., when tissue microarray samples are collected), will no longer be linked to you. If you change your mind and your samples have already been tested, those results will still remain as part of the overall research data. In the event of your death or loss of competence, your specimens and data will continue to be used as part of the RBR. If you withdraw or discontinue from the main study, your RBR samples will continue to be stored and used for research unless you specifically ask that they be destroyed.

Signature

I willingly consent to allow my samples to be stored in the RBR and used for the types of research outlined above.

Patient name (print)	
If applicable – Name of patient's legally authorized representative (print)	Relationship to patient
Patient signature or signature of patient's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the patient named above and/or the patient's legally authorized representative.

Name of person conducting informed consent discussion (print)	
Signature of person conducting informed consent discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

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