



# PHOENIX

A trial to look for markers in the tumour cells and blood which signal that trial treatments are working in a patient with triple negative breast cancer, for whom upfront chemotherapy has not provided the maximum expected benefit

## PATIENT INFORMATION SHEET FOR CONTINUATION TO PART 2: COHORT B (AZD6738)

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### Invitation to continue to Part 2 of the PHOENIX clinical trial

- You have been given this patient information sheet because you already agreed to take part in PHOENIX and received AZD6738 trial treatment before your surgery, and you may be suitable for Continuation to Part 2 of the trial.
- Before you decide whether to continue to Part 2, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read this information sheet carefully and discuss it with friends, relatives and your GP if you wish.
- Ask your trial doctor or nurse if there is anything that is not clear or if you would like more information.
- Please take as much time as you need to decide whether or not you wish to **continue to Part 2 of the PHOENIX trial**.

### Important things to know

- This information sheet provides information you will need to know to make an informed decision about whether to continue to Part 2 of the PHOENIX trial.
- In this information sheet you will find further details on why we are doing this trial, why you have been invited to continue to Part 2 and what will be involved if you decide to participate further.

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### **Why am I being invited to take part in PHOENIX Part 2?**

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You have been invited to continue to Part 2 of the PHOENIX trial because:

- You previously agreed to take part in PHOENIX and received trial treatment with AZD6738 between completing chemotherapy and having surgery
- Trackable mutations were identified in your tumour tissue sample that you agreed to provide at Trial Registration; so you are suitable to consider continuation to Part 2 of the PHOENIX trial.

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### **Do I have to take part?**

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No, it is up to you to decide whether or not to continue to Part 2. Your participation is entirely voluntary and you will be given sufficient time to decide whether or not you wish to participate. Your decision to continue to Part 2 or not will not affect the standard of care you receive. If you do decide to take part you are free to withdraw at any time and do not have to give a reason.

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### **A reminder of the purpose of PHOENIX**

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We know that in some patients, triple-negative breast cancer (TNBC) can have a high or moderate risk of coming back (or relapsing) after standard treatment. This usually happens within the first two years after finishing standard treatment. We also know that in some patients with TNBC who receive chemotherapy before surgery, if there is cancer remaining after chemotherapy (called residual disease) that risk of relapse is higher.

In PHOENIX we want to look at the biology of the residual disease in the 2-week time window between completing chemotherapy and having surgery. We want to see if taking trial treatment in this window changes the biology of the residual disease. In order to do so we will compare tumour tissue and blood samples collected prior to trial treatment with tumour tissue and blood samples collected after trial treatment but before surgery. If a difference is seen this may be an early sign that the trial treatment could be used to treat this type of cancer in future and may support further investigation over a longer period of time.

Safety and tolerability of the trial treatments have been, and will continue to be, monitored closely in this trial. No new safety concerns relating to treatment with AZD6738 have been raised in this trial to date so you are now being given the option to continue to Part 2 of the PHOENIX trial to confirm if you are suitable to resume trial treatment after surgery (called the adjuvant setting). The purpose of giving trial treatment in the adjuvant setting is to investigate whether any biological activity seen within the residual disease after taking trial treatment in the short 2-week window before surgery is also seen after longer exposure to trial treatment over 12 months.

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### **What will happen if I decide to continue to PHOENIX Part 2?**

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If you agree to continue to Part 2 you will be given this information sheet to keep and you will be asked to sign a consent form for **Continuation to Part 2 of the PHOENIX Trial**.

In order to determine if you may be suitable to resume trial treatment within Part 2, you will be asked to provide a blood sample (30ml which is equivalent to approximately 6 teaspoons) which will be sent to the trial central laboratory at The Institute of Cancer Research and Royal Marsden NHS Foundation Trust where “circulating tumour DNA” or ctDNA screening will be performed.

When cells die they release pieces of DNA into the blood stream. The DNA from cancer cells found in the blood is known as ctDNA. It is thought that the presence of ctDNA in the blood can be an early indication that the cancer is at greater risk of relapsing or spreading to another part of the body.

To test for the presence of ctDNA in the blood, a tumour tissue sample needs to be analysed to see if there are particular mutations present that are called “trackable mutations”. A sample of your tumour tissue has already been tested for trackable mutations and you have been given this information sheet because trackable mutations have been identified in your tumour tissue, which can be used to test for the presence or absence of ctDNA in your blood.

We estimate that it will take approximately 2 weeks for the results to be returned to your trial doctor, although in some circumstances results may take longer. We will also ask for information in your medical records to be provided to us by the research team at your hospital.

In some cases you may be asked by your trial doctor or research nurse to provide a further blood sample in order to complete ctDNA screening. This may happen if the analysis fails due to technical difficulties in the central laboratory or if the analysis needs to be repeated to confirm the result and there is not enough blood left to do so. You are under no obligation to provide a further blood sample, it is your decision as to whether or not you wish to do so however if the result is not confirmed then you will not have the option to resume trial treatment in Part 2.

Based on previous research, we think that approximately a fifth of all PHOENIX participants may have ctDNA identified in the ctDNA screening blood sample collected 30 days or 3 months after surgery.

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**What will happen if ctDNA is found in my blood sample?**

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If ctDNA is found to be present in the blood sample you provided for ctDNA screening you will need to have some assessments to check that you are suitable to resume trial treatment in Part 2.

The assessments may all be done together during one visit, or across a few visits. Your doctor will talk to you about this.

The assessments are outlined in the following table:

Pre-treatment assessment	Further details
Imaging (bone scan and CT scan, or FDG PET-CT scan)	<p>You will be asked to have an additional bone scan and CT scan or FDG PET-CT scan to show whether the cancer has spread to another part of the body:</p> <ul style="list-style-type: none"> <li>• If the scan shows no evidence that the cancer has spread to other parts of the body, it may be possible for you to resume trial treatment for 12 months in Part 2 provided that you are suitable to receive trial treatment after the assessments listed below have been performed.</li> <li>• If the scan shows evidence that the cancer has spread to other parts of the body, your doctor will be able to discuss treatment options available to you outside the PHOENIX trial.</li> </ul>
Review of your current health and medication	To check that you are suitable to resume trial treatment in Part 2.
An electrocardiogram (ECG)	To assess your heartbeat rhythm.

<b>Pre-treatment assessment</b>	<b>Further details</b>
Physical examination	Including weight, blood pressure, heart rate and temperature.
Collection of blood samples for routine tests	Approximately 3 teaspoons (15ml) of blood will be taken for routine safety checks to confirm you would be suitable to resume trial treatment in Part 2.
A pregnancy test	A pregnancy test will be carried out for all women who are able to get pregnant.

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### **What will happen if ctDNA is not found in my blood sample or tests show I am not suitable to resume trial treatment in Part 2?**

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If ctDNA is not found to be present in the blood sample you provided for ctDNA screening or tests show your cancer has not spread to other parts of the body, but you are not suitable to resume trial treatment in Part 2 we will continue to collect blood samples from you every 3 months for a period of 24 months for research into TNBC.

<b>Timing of blood sample collections for patients not resuming trial treatment</b>		
<b>Type of blood sample</b>	<b>Amount of blood that will be taken</b>	<b>Timing of collection</b>
Research blood sample to explore ctDNA and biomarkers which may help to predict how well treatment will work for individuals	20ml (4 teaspoons)	Every 3 months for up to 2 years (8 samples in total)

We will also continue to collect information from your hospital on how you are getting on and about any further treatments you may receive in future. If available, we would also like to collect any tissue samples taken as part of your routine care if your cancer comes back while you are still being followed up for the trial.

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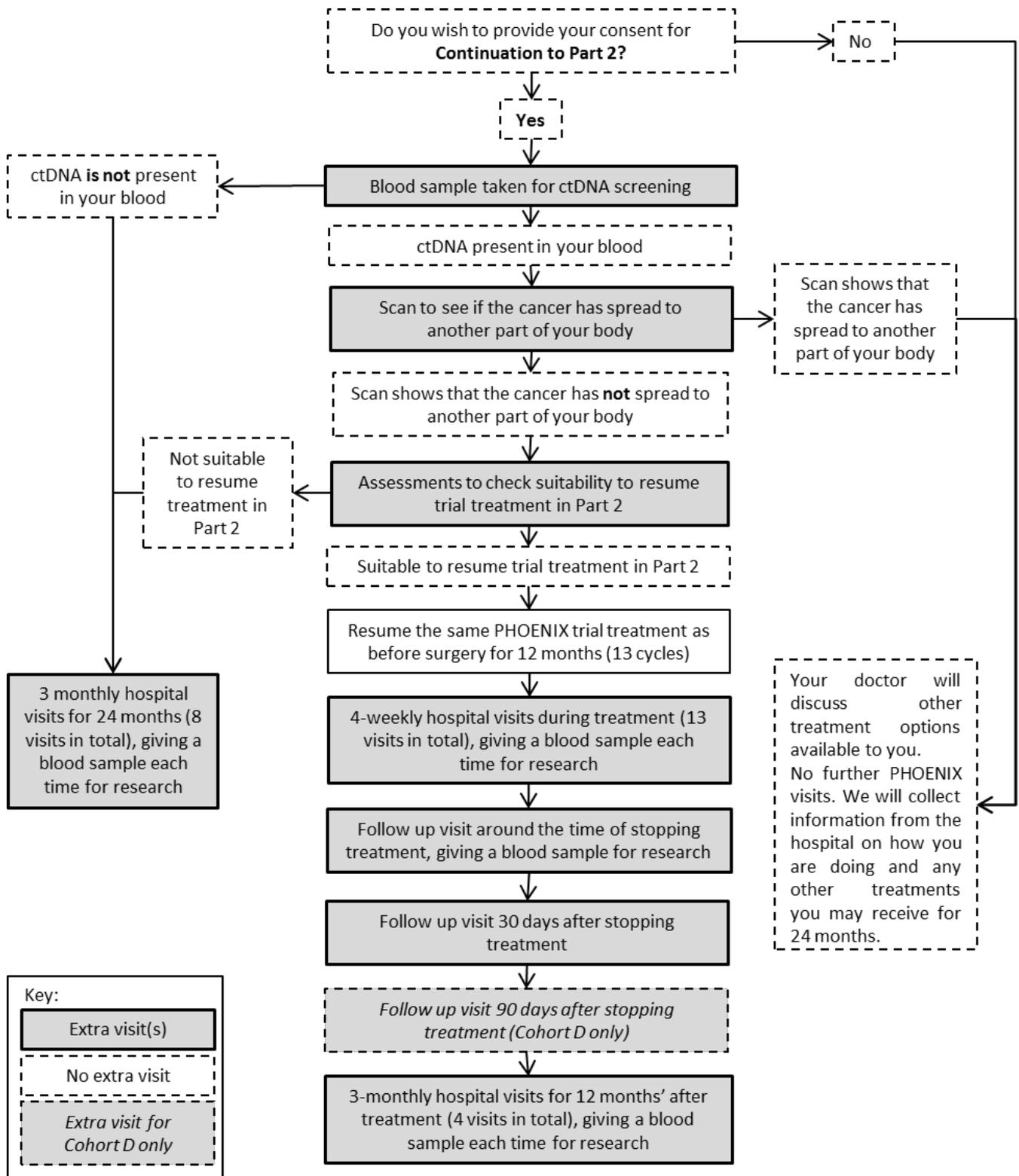
### **What if I decide that I do not want to take part?**

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If you decide you do not want to participate any further your doctor will discuss the treatment options available outside this trial with you.

## PHOENIX Part 2 Flow Chart

The following flow chart sets out the steps involved if you continue to Part 2. Some steps will involve extra visits to the hospital.



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**How should AZD6738 be taken in Part 2?**

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If you are confirmed as suitable to resume trial treatment in Part 2, you will take trial treatment in 4 weekly cycles for up to 12 months (13 cycles).

You will be given a sufficient supply of AZD6738 tablets for 4 weeks to take home with you. AZD6738 tablets should be taken orally twice a day. You should not eat any food for 2 hours before and 1 hour after taking your tablets. Drinking water in those 2 hours is ok. The tablets should be taken whole and should not be split, chewed, crushed or dissolved.

You will need to take a total dose of 320mg per day (160 mg twice a day, days 1- 14). This should be taken as two separate 160mg doses taken at the same times each day approximately 12 hours apart. You will do this every day for Days 1–14 followed by 14 days of no trial treatment for each 4 week cycle, or as directed by your trial doctor or research nurse. You may take your AZD6738 tablets up to 2 hours after the scheduled dose time. Each 4-week block will be one treatment cycle. If you forget to take a dose of AZD6738 and if more than 2 hours has passed since your scheduled dose time or you are sick shortly after taking a dose of AZD6738 you should continue to take the next dose as scheduled. You should not take extra tablets to make up a missed dose.

Please store your AZD6738 tablets at room temperature and out of direct sunlight. There may be some tablets left in the bottle at the end of each cycle, and you should bring any empty bottles and bottles containing the leftover tablets to the clinic visit after completing trial treatment.

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**How long will I receive trial treatment for in Part 2?**

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You will receive trial treatment in 4 weekly cycles for 12 months (13 cycles), unless your cancer gets worse (progresses), or you need to stop due to side effects of the treatment.

When you stop taking trial treatment your doctor will discuss with you what your next options for treatment are.

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**What assessments will be required if I resume trial treatment in Part 2?**

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You will have regular clinic visits to monitor your progress and any side effects while taking trial treatment in Part 2.

These visits will take place:

- Within 3 days before resuming trial treatment in Part 2 (Cycle 1)
- Up to 3 days before starting Cycle 2, before taking your first dose for the next cycle
- Up to 3 days before starting Cycles 3-13, before taking your first dose for the next cycle

You need to consider carefully how these assessments and hospital visits will affect you and your family. Please ask your doctor or nurse if you have any questions about the assessments.

During the clinic visits you will also have regular assessments and routine blood tests, and 13 research blood sample collections, as outlined in the following tables:

Timing of assessments in clinic during treatment	
Assessment	Timing of assessment
Discussion with your trial doctor to document changes in your health or medications since your last visit	<ul style="list-style-type: none"> <li>• Within 3 days before resuming trial treatment in Part 2</li> </ul>
Physical examination including weight, blood pressure, heart rate and temperature	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>
ECG to assess your heartbeat rhythm	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>
Review of your completed patient diary card for the previous cycle	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>
Pregnancy test for all women who are able to become pregnant	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>

Timing of blood sample collections during treatment		
Type of blood sample	Amount of blood that will be taken	Timing of collection
Routine blood tests for routine safety checks	15ml (3 teaspoons)	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>
Research blood sample to explore ctDNA and biomarkers which may help to predict how well treatment will work for individuals	20ml (4 teaspoons)	<ul style="list-style-type: none"> <li>• Up to 3 days before starting cycle 2</li> <li>• Up to 3 days before starting cycles 3-13</li> </ul>
<b>Research blood samples taken before starting cycles 2–13 will need to be taken before you receive your first dose of trial treatment for that cycle, so you should wait to start your tablets until after your blood samples have been collected.</b>		
The maximum amount of blood that will be collected for research purposes at any clinic visit is 35ml (7 teaspoons).		

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### What happens once I stop taking trial treatment?

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You will need to visit the hospital when you finish cycle 13 of treatment for assessments to be performed. In case your doctor decides that you should stop treatment earlier than planned, or you decide you want to stop taking treatment for any reason, the assessments might be done at the next planned visit.

You will also need to visit the hospital 30 days after the last treatment cycle. At this visit your trial doctor and research nurse will check any medications you are taking, ask if you have any lasting side effects and conduct a physical examination and perform blood tests for routine safety checks.

After you stop trial treatment you will have to attend the hospital every 3 months for a further 12 months (or total of 24 months from your 3 month post-surgery visit if you stop trial treatment early) to have a research blood sample collected. If your cancer comes back during this time, we would also like to collect any tissue samples taken as part of your routine care. After this time we would also like to keep in touch with your doctor to continue to collect information about your health status, ideally we would like to do this for life.

<b>Assessments after stopping treatment</b>		
<b>Assessment</b>	<b>Further details</b>	<b>Timing of assessment</b>
Medication and symptoms review	Discussion with your trial doctor to document changes in your health or medications since your last visit	<ul style="list-style-type: none"> <li>around the time of stopping trial treatment</li> <li>30 days after stopping trial treatment</li> </ul>
Physical examination	Including weight, blood pressure, heart rate and temperature	<ul style="list-style-type: none"> <li>around the time of stopping trial treatment</li> <li>30 days after stopping trial treatment</li> </ul>
ECG	To assess your heartbeat rhythm	<ul style="list-style-type: none"> <li>around the time of stopping trial treatment</li> <li>30 days after stopping trial treatment</li> </ul>
Pregnancy test for all women who are able to become pregnant		<ul style="list-style-type: none"> <li>30 days after stopping trial treatment</li> </ul>

<b>Timing of blood sample collections after stopping treatment</b>		
<b>Type of blood sample</b>	<b>Amount of blood that will be taken</b>	<b>Timing of collection</b>
Routine blood tests for routine safety checks	15ml (3 teaspoons)	<ul style="list-style-type: none"> <li>around the time of stopping trial treatment</li> <li>30 days after stopping trial treatment</li> </ul>
Research blood sample to explore ctDNA and biomarkers which may help to predict how well treatment will work for individuals	20ml (4 teaspoons)	<ul style="list-style-type: none"> <li>around the time of stopping trial treatment</li> <li>at each 3-monthly visit after stopping trial treatment, for 12 months (4 visits) or total of 24 months from your 3 month post-surgery visit if you stop trial treatment early</li> </ul>

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### **What are the side effects of treatment?**

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As with any treatment, AZD6738 can have side effects. No-one can predict before you begin treatment whether you will have any of these, or how serious they might be. AZD6738 is an experimental drug without a license and therefore the frequency of some of the listed side-effects is not certain. Side

effects that have been previously reported are listed below. Not all patients will experience these side effects and medications can be given to make them less serious or less uncomfortable. There may also be risks involved in taking this medication that have not been identified in the studies done so far, so please report anything that is troubling you to your trial doctor. Your progress will be closely monitored and your doctor will offer whatever help is available to cope with any side effects observed. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious.

**Side effects which are very common (occurring in at least 10 patients out of 100, ≥10%)**

- Decrease in red blood cells (anaemia) – this can cause tiredness and breathlessness and you may need a blood transfusion
- Decrease in platelets (thrombocytopenia) – this may increase your risk of bleeding
- Decrease in white blood cells (neutropenia and leukopenia) – this can increase your risk of an infection. **You should contact your trial doctor or nurse straight away if you feel unwell or if your temperature goes above 38°**
- Nausea
- Vomiting

**Side effects which are common (occurring in between 1 and 10 patients out of 100, ≥1% to <10%)**

- Febrile neutropenia
- Diarrhoea

There is also a theoretical risk that AZD6738 might make you more sensitive to the sun, so please take care not to get excessive sun exposure whilst taking this drug and take precautions (*e.g. use of high factor sun cream, long sleeved clothing/trousers, wearing a hat etc.*)

There is a risk that AZD6738 might cause you to feel dehydrated, if this happens your doctor might offer you some supportive treatment to help with this.

All drugs have the potential risk of an allergic reaction which if not treated promptly could become life threatening. **You should seek medical advice and contact your trial doctor or research nurse immediately if you have trouble breathing or have swelling of the face, mouth, lips, gums, tongue or neck.**

It is important that you report all symptoms and side effects that you may experience to your trial doctor or research nurse as soon as they occur, whether or not you think they are caused by the trial treatment so they can advise you what to do.

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**Can I take other medication while participating in PHOENIX Part 2?**

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There are certain groups of medications that you will not be allowed to take while you are in this treatment cohort because of the way they interact with trial treatment. These medications include certain antibiotics, anti-fungal treatments, HIV treatments, anticonvulsant drugs, calcium channel

blockers and antidepressants. You should inform your trial doctor of any medications that you are taking, and if necessary they will try and find an alternative for you. If there is no alternative you may not be able to take part in this treatment cohort. You will not be asked to stop any medications that you need. Some herbal and dietary supplements and some vaccinations may interact with trial treatment, so need to be discussed with your doctor before they are taken.

You should avoid consumption of grapefruit, grapefruit hybrids, pummelos, star-fruit, Seville oranges or products containing the juice of any of these (such as marmalade) during the entire trial and preferably 7 days before the first dose of trial treatment.

If you begin taking any new medications or supplements while participating in the trial, please inform your trial doctor as soon as possible.

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### **Will there be anything extra I need to do if I continue to Part 2?**

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If you decide to continue to Part 2, you will need to:

- Sign the consent form for Continuation to Part 2 to show you understand what participation involves.
- Attend all scheduled appointments.

If the assessments show you are suitable to resume trial treatment, you will also need to:

- Take your trial treatment as directed.
- Complete your patient diary card as directed.
- Only take the trial treatment yourself.
- Store any medication provided to you in the bottle given to you by your trial doctor or pharmacist as directed on the label.
- Keep your treatment out of the reach of children.
- Talk to your trial doctor or nurse first if you want to stop taking the trial treatment for any reason.
- Report all symptoms and side effects that you may experience to your trial doctor or research nurse as soon as they occur, whether or not you think they are caused by the trial treatment.
- Tell your doctor about any other medicines that you take, even if you buy them without a prescription; this includes over the counter medications or herbal supplements.
- Tell your doctor about any medical problems you have.
- Return any medicine containers (with any leftover tablets) to the trial team at each visit.

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### **What are the possible benefits of taking part?**

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It is important to note that you may not get any direct benefit from participating in PHOENIX. However, your participation is likely to help us identify whether any of the trial treatments could be effective for the treatment of TNBC. We hope that the trial will help to select those treatments which should be further investigated in a larger clinical trial to see if they are better than the treatments currently offered, and find answers to questions that could help to improve the treatment for future patients with TNBC.

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### **What are the possible disadvantages and risks of taking part?**

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The disadvantages and risks of taking part are detailed below:

**i. Additional hospital visits:**

Taking part in this trial will involve several additional visits to the clinic. This may cause some disruption to your normal activities and home life and this should be discussed with your family and friends if it will impact on them. We will be able to reimburse you for any extra travel expenses; your doctor will discuss this with you.

**ii. Blood tests:**

As shown in the flow chart on page 7 of this information sheet, taking part in the PHOENIX trial requires you to give several blood samples. The number of blood samples required in this trial is more than if you were receiving standard care outside this research trial. Risks linked with collecting blood samples from your arm include pain from the needle being inserted, bruising, light-headedness, possible fainting and (rarely) infection.

**iii. Electrocardiogram**

The electrocardiogram for the electrical tracing of your heartbeat involves placing small electrodes on the surface of your skin. Rarely, a slight redness or inflammation may appear due to the adhesives used to attach the electrodes to the skin.

**iv. Radiation exposure**

By continuing to PHOENIX Part 2 you will have an additional bone scan and CT scan or FDG PET-CT scan if ctDNA is found in the blood by ctDNA screening. These procedures involve some exposure to ionising radiation. In total the additional radiation dose you may receive from this part of the trial would be equivalent to approximately 13 years of background radiation. Ionising radiation can have an adverse effect on the body, including a small increased risk of about 0.2% causing a cancer several years after the exposure. However, in this case the benefits outweigh any such risk as the additional scan will allow your doctor to monitor the progress of your cancer to detect as early as possible if your cancer has grown.

**v. Side effects of trial treatment:**

AZD6738 is an unlicensed drug, which means that it is regarded as experimental and not all of the side effects are yet known. You may therefore experience some side effects that are not anticipated and are not listed in the previous sections. There is no way of predicting if you will experience any side effects, or how severe they will be. You should contact your trial doctor if you experience any side effects, even if you are not sure that any problems you may have are related to taking the trial treatment. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious.

**vi. Risks to an unborn child**

There could be risks to an unborn child if you receive trial treatment; therefore, if you are pregnant you cannot enter the trial. If you become pregnant during the trial, these risks could affect you or your unborn child. Before commencing trial treatment, during trial treatment and at the end of trial treatment, pregnancy tests will be carried out for all women who are able to get pregnant. If applicable, you must agree to practice total abstinence or to use a condom and one highly effective form of contraception in combination (as listed below) during trial treatment and for a period of at least 6 months after the last dose of trial treatment.

**Highly effective birth control methods used must include ONE of:**

- Vasectomised sexual partner. With assurance that the vasectomised partner has received post-vasectomy medical confirmation of surgical success (azoospermia).

- Bilateral tubal occlusion.
- Intrauterine device (IUD). Provided coils are copper-banded.
- Combined (estrogen and progestogen containing) oral hormonal contraception pill associated with inhibition of ovulation.
- Cerazette (desogestrel).
- Hormonal injection (e.g. Depo-Provera).
- Etonogestrel implants (e.g. Implanon, Norplant).
- Norelgestromin / ethinyl estradiol (EE) transdermal system.
- Intrauterine system (IUS) device (e.g. levonorgestrel releasing IUS -Mirena®).
- Intravaginal device (e.g. EE and etonogestrel).

If you think you may be pregnant, you must tell your trial doctor immediately. Pregnancy will be a reason to stop trial treatment. If you become pregnant, information on the outcome of your pregnancy will be requested.

#### **vii. Private medical insurance**

If you have private medical insurance you should check with the insurance company before agreeing to take part in this trial to ensure that your participation will not affect your cover.

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#### **What will happen to my blood and tissue samples?**

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We ask that all patients continuing to Part 2 of the PHOENIX Trial donate blood samples for research during the trial. Details of the samples requested throughout PHOENIX are described in the flow chart on page 7 of this information sheet.

We would also like to collect any samples taken as part of your routine care if your cancer comes back once you have finished trial treatment but while you are still being followed up for the trial. Any samples you donate will be used to help us understand how cancer, in particular TNBC, reacts to trial treatment.

Blood and tissue samples that you donate in the PHOENIX trial will be sent to the trial central laboratory at The Institute of Cancer Research and Royal Marsden NHS Foundation Trust where they will be securely stored.

All your samples will be labelled with your initials, date of birth, date of sample and unique Trial ID Number when they are sent to the central laboratory so we can identify each sample. When they arrive at the trial central laboratory, a unique laboratory code will be allocated to each sample. The coding will maintain your confidentiality whilst allowing biological details to be compared to clinical findings.

Some of your samples will stay at The Institute of Cancer Research and Royal Marsden NHS Foundation Trust for laboratory researchers to look at to see what the PHOENIX trial has found. In all cases, your confidentiality will be maintained.

In addition, we would like to use your samples for further research within the PHOENIX trial. For such research it may be necessary to use commercial companies to carry out tests on the samples. For example, in situations where the research organisations do not have access to specialist equipment and/or where using a commercial company may be more cost-effective because they can carry out a greater volume of tests within a short time frame. In such cases, after testing is complete the commercial company would return all result data and any surplus samples to the research organisation and would not be permitted to use the data or samples for their own research.

As explained in the PHOENIX Patient Information Sheet for Trial Entry, in order to gather more information, we may share your samples and/or information we gain from your samples, including genetic details, with other cancer researchers at other specialist research laboratories in the UK, the EU or outside the EU. Your samples and information about your cancer will be anonymised before they are shared, meaning you cannot be identified from the sample/information. This will not affect your care or influence whether or not you receive PHOENIX trial treatment.

If you previously gave your permission during consent for Trial Entry, after the PHOENIX trial is complete, any leftover samples will be stored at the trial central laboratory for use in future medical research that may involve research by other health and research organisations.

Any research using your samples will have approval from a Research Ethics Committee and you will not be identifiable from the sample. If any future research undertaken leads to a new treatment or test that becomes commercially viable, you will not benefit financially from this.

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#### **How will confidentiality be maintained?**

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The Institute of Cancer Research is the sponsor for this trial based in the United Kingdom. We will be using information from you and your medical records in order to undertake this trial and will act as the data controller for this trial. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the trial has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the General Data Protection Regulation (GDPR).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at [www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency](http://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency).

**[Insert appropriate name for NHS site]** will collect information from you and your medical records for this research trial in accordance with our instructions.

**[Insert appropriate name for NHS site]** will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to contact

you about the research trial , and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial.

All information which is collected about you during the trial will be kept strictly confidential. When you entered the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number was passed to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) where the trial is being coordinated. You were given a unique Trial ID Number, which is used together with your initials and date of birth on forms that the research staff at your hospital send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams working on PHOENIX will have access to the information that could allow this Trial ID Number to be linked to you.

As explained in the PHOENIX Patient Information Sheet for Trial Entry, from time to time we would like to know how you are getting on. Ideally ICR-CTSU would like to do this for life, and we would like to use national records, which are kept on everyone's health status to find out how you are. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your full name, date of birth postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, the Medicines and Healthcare products Regulatory Agency (MHRA) and ethics committee approving the trial, the pharmaceutical company, AstraZeneca, which manufactures the trial drug and may have offices outside of the UK/EU, and third parties approved by ICR-CTSU may need to examine your medical records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

**[Insert appropriate name for NHS site]** will keep identifiable information about you from this trial for at least 5 years after the trial has finished.

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## Data sharing

As explained in the PHOENIX Patient Information Sheet for Trial Entry, when you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research:

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Our main privacy policy can be found at <https://www.icr.ac.uk/legal/privacy>. If you have any questions about your rights under the United Kingdom General Data Protection Regulation (UKGDPR) or how we

use your information please contact our Data Protection Officer at [dataprotectionofficer@icr.ac.uk](mailto:dataprotectionofficer@icr.ac.uk).

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### **Involvement of your General Practitioner (GP)/family doctor**

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Your GP was previously informed about your participation in the PHOENIX trial. This will ensure that your GP knows you are taking trial treatment in the event of any potential side effects and/or drug interactions.

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### **What if there is a problem?**

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If you have any concern about any aspects of the trial you should first ask to speak with your trial doctor or research nurse, who will try to resolve the problem. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this trial, you may do so under the standard National Health Service (NHS) complaints procedure, which is available to you at your doctor's hospital. We recommend that you obtain a copy of your hospital's complaints procedure or policy if you intend to make a complaint.

**[Sites in England]** Concerns can also be raised by talking to your local Patient Advice and Liaison Service (PALS). You can contact the PALS team at **[insert Trust name]** on **[insert relevant contact details]**.

**[Sites in Scotland]** Concerns can also be raised by talking to the Patient Advice and Support Service (PASS). You can contact PASS via the National Citizens Advice Bureau on 0808800 9060 or through your local Citizens Advice Bureau ([www.cas.org.uk/patientadvice](http://www.cas.org.uk/patientadvice)).

**[Sites in Wales]** Concerns can also be raised by talking to the Patient Support and Advisory Service (PSAS). You can contact PSAS on 0300 0200 159 or emailing [hdhb.patientsupportservices@wales.nhs.uk](mailto:hdhb.patientsupportservices@wales.nhs.uk).

**[Delete above sections as appropriate for location of trial site.]**

You will be closely monitored both during and after treatment and any side effects will be treated as appropriate. If you suffer any side effects or injury, please notify the trial doctor immediately so you can obtain appropriate medical attention.

In the unlikely event that you are injured by taking part, compensation may be available. If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action but you might have to pay for it. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals that are under their care and covered under the NHS Indemnity Scheme.

If you suffer adverse side effects of the trial treatment or harm caused by procedures you have undergone specifically for the trial you may be able to claim compensation from The Institute of Cancer Research as Sponsor of the PHOENIX trial. In deciding the level of compensation to be awarded, consideration will be given to the likelihood of side effects and any warnings that were given.

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### **What happens if I don't want to carry on with the trial?**

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Your participation is voluntary. If you agree to take part and then change your mind later on, you can withdraw from the trial at any point without giving a reason. If you withdraw from the trial, it will not affect the standard of care you receive. Your trial doctor will discuss alternative treatment with you and offer you the most suitable treatment available.

If you should withdraw fully from the trial, trial data collected before your withdrawal may still be processed along with other data collected as part of the clinical trial. However, you may request that all retained identifiable samples are destroyed to prevent future analysis.

You will be asked to return to the clinic to undergo the tests and evaluations scheduled for the safety follow-up visit. You retain the right to decide whether data from the visit can be used.

If you were to withdraw from the trial, and you previously gave your permission, your hospital will continue to send basic clinical information on your progress that would routinely be collected and written in your medical records to ICR-CTSU. This is so that the overall quality of the trial is not impaired.

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**What if I have private medical insurance?**

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If you have private medical insurance please check with the company that your medical insurance policy will not be affected before agreeing to take part in this trial.

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**Who is funding and organising the trial?**

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The trial is funded by AstraZeneca, the pharmaceutical company who manufacture the trial treatments (AZD6738, olaparib and durvalumab). AstraZeneca are supplying the trial treatments free of charge and providing additional funding to support the management of the trial.

The trial is organised by the Institute of Cancer Research (led by Professor Andrew Tutt). The trial is coordinated by The Institute of Cancer Research Clinical Trials & Statistics Unit (ICR-CTSU). The trial is being carried out by a network of doctors across the UK. The trial funding helps to cover the cost of including information about you in the trial, the laboratory tests and helps support the research staff. None of the researchers are personally benefiting from this funding.

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**Who has reviewed the trial?**

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Cancer Research UK has reviewed PHOENIX and supports the aims of the trial. PHOENIX has also been approved by the UK Regulatory Agency (Medicines and Healthcare Regulatory Agency, MHRA), a Research Ethics Committee (London - South East Research Ethics Committee) and the Health Research Authority (HRA). Their approval means they are satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given the right information to decide whether to take part.

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**What will happen to the results of the trial?**

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Independent experts will review the progress of the research, and the results will be published in a scientific journal as soon as there is enough information to be sure the results are reliable. Once available, the results will also be available on the Cancer Research UK trials database (<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial>).

The results will help to decide which treatment we should look at more closely in a bigger clinical trial and how to treat patients with TNBC in the future. The results from this trial may also contribute to reviews of worldwide evidence about this type of cancer and its treatment. You will not be identified in any report or publication relating to this research.

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**What if relevant new information becomes available?**

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Sometimes during the course of a trial, new information becomes available about the trial treatments being studied. If this happens, your trial doctor will tell you about it and discuss whether you want to, or should, continue in the trial. If you decide not to carry on, your doctor will make arrangements for your continued care. If you decide to continue in the trial you may be provided with an updated information sheet and asked to sign an updated consent form.

If the new information means it would be in your best interests to withdraw you from the trial, your doctor will explain the reasons for this and arrange for your continued care. If the trial is stopped for any other reason, you will be told why and your doctor will arrange for your continued care.

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**What happens now?**

Your doctor or nurse will be happy to answer any questions. Once you have reached your decision please let your doctor or nurse know. If you choose to consent for Continuation to Part 2 of the PHOENIX trial you will be asked to sign a consent form and will be given a copy to keep together with this information sheet.

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**Further information**

**Macmillan Cancer Support** is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families.

You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line; Freephone 0808 808 00 00, Monday to Friday, 9.00am to 8.00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

You can learn more about clinical trials and the results of this trial once available on the Cancer Research UK's patient website (<http://www.cancerresearchuk.org/cancer-help/trials/>).

**Thank you for taking the time to consider taking part in this trial.**

**Your specialist is:**

**Contact phone numbers:**

