(To be printed on local hospital headed paper)

RE-AKT

A trial of the combination treatment enzalutamide and AZD5363 for patients with advanced prostate cancer.

PATIENT INFORMATION SHEET

Phase II Expansion Trial

CANCER RESEARCH UK

RE-AKT: A trial of the combination treatment enzalutamide and AZD5363 for patients with advanced prostate cancer.

We are inviting you to take part in a clinical study

- We are inviting you to take part in a clinical trial called RE-AKT. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us 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 take part in the RE-AKT study.
- Part 1 of this information sheet tells you about the purpose of the study and what taking part will involve for you. Part 2 gives more detailed information about the biological research we would like to carry out on samples that we will ask you to donate if you decide to join RE-AKT.

Contents

How to contact us

If you have any questions about this study, please talk to your doctor at
<Hospital Department>
<Hospital>
<Address>
<Address>
Tel: <01234 XXX XXX>

Part One: About the RE-AKT trial

1 Important information

What is the purpose of the RE-AKT study?

We are aiming to find out if a new combination treatment of 2 drugs called enzalutamide and AZD5363 is well tolerated and more effective than giving enzalutamide on its own to control your cancer. We also want to find out who will be helped the most by the combination treatment by looking at the way your cancer reacts to the drugs, what happens to the drugs inside the body and what the drugs do to the body.

What is the combination treatment?

The combination treatment includes a drug called enzalutamide (which you have already been taking) and a drug called AZD5363.

- **Enzalutamide**

Enzalutamide is a newly approved (licensed) drug for the treatment of men with advanced prostate cancer who have already received treatment with docetaxel chemotherapy. It

already received treatment with docetaxel chemotherapy therapy. It comes in capsule form and is taken once per day.

Enzalutamide is a type of drug called an androgen receptor antagonist. It works by blocking a number of steps in the process by which male hormones (androgens) signal to the cancer cell to grow.

- **AZD5363**

AZD5363 is a new, unlicensed, drug which is being investigated in this clinical trial. AZD5363 has been studied in the laboratory and clinic, and has fulfilled the necessary requirements for the regulatory agencies to agree it can be given to patients in a clinical trial. AZD5363 comes in tablet form and is taken twice per day for 4 days and then no tablets for 3 days.

AZD5363 is a drug which inhibits a protein called AKT which helps cancer cells grow, multiply and spread. If we can stop this process with AZD5363 we think it could slow the growth and spread of prostate cancer.

Even though your cancer has become resistant (is no longer responding) to enzalutamide (given alone), there is a chance that by adding the new drug AZD5363 this resistance can be reversed and the combination may stop or slow further growth or spread of cancer cells.

Why am I being invited to take part?

You have been diagnosed with advanced (also called metastatic) prostate cancer that is no longer responding to enzalutamide. You have been approached because your doctor feels that you may be suitable to take part.

If you join the study, you will be one of about 18 men taking part.

Do I have to take part?

No, it is up to you to decide whether or not to take part in RE-AKT. If you decide to take part you are free to leave the study at any time and do not have to give a reason. Whether or not you decide to join the RE-AKT study will not affect the standard of care you receive.

2 What will happen to me if I decide to take part?

If you agree to take part in the RE-AKT study you will be given this information sheet to keep and asked to sign a consent form to register for the study. You will need to have a number of examinations before you can join the study. Some of these are routine, but others will need to be done to make sure that it is appropriate and safe for you to take part.

They may take up to 4 weeks to complete and include;

- a physical examination, including your heart rate, breathing rate, blood pressure, height and weight
- an electrocardiogram (ECG) to assess your heart rhythm
- an echocardiogram (ECHO) or a MUGA (multiple gated acquisition scan) to assess your heart function
- a blood sample (approximately 37mls or 7 teaspoons) for routine safety checks and assessment of your PSA (prostate specific antigen) level.
- a computed tomography (CT) scan of your chest, abdomen, pelvis and if necessary other areas to assess your cancer
- a bone scan to evaluate the spread of cancer to your bones

Biological samples will be collected for research into your disease;

- a blood sample (approximately 61mls or 12 teaspoons)
- a urine sample collected over 24 hours
- a swab of the inside of your cheek (buccal swab)
- spitting into a small container to collect saliva
- collection of tissue that has already been taken from you tumour (during biopsy) and

stored. If an existing tissue sample is not available then we will ask you to have a biopsy.

- a tumour biopsy from your prostate or from a site to which your cancer has spread.

What if the tests show that I am not suitable for the RE-AKT study?

Your doctor will discuss the alternatives to participating in this study with you.

3 What if the tests show that I am suitable for the RE-AKT study?

If after the tests your doctor thinks that you are suitable for RE-AKT and if you agree to continue in the study you will need to have a number of examinations at the hospital before you can start treatment. Once these have been performed you will be given a supply of your study treatment.

If you have recently stopped taking Enzalutamide in the last 12 weeks you will start combination treatment straight away. If you stopped taking Enzalutamide over 12 weeks ago, your doctor will restart you on Enzalutamide treatment for at least 4 weeks. During this time your PSA level will be monitored by your doctor who will advise you the best time to start combination treatment.

The first day you take combination treatment will be called cycle 1. Each cycle lasts 28 days (4 weeks). You will need to take your treatment each week as described in the table below.

What are the side effects of the study treatment?

As with any drug, enzalutamide and AZD5363 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. The side effects of each drug that have been reported in previous studies are listed below. **Not all patients will experience all of these side effects and medications can be given to make any side effects less serious or uncomfortable.**

- **Enzalutamide**

Very common side effects (may affect more than 1 in 10 people):

- hot flushes
- hypertension (high blood pressure)
- fractures (break in the bone)

Common side effects (may affect up to 1 in 10 people):

- visual hallucinations
- anxiety
- cognitive disorder (things that affect learning, memory, perception, and problem solving)
- amnesia (loss of memory)
- trouble concentrating or focusing on one thing
- dry skin
- pruritus (itching)
- falling over
- coronary heart disease
- headache

Uncommon side effects (may affect up to 1 in 100 people):

- seizure (fits)

Rare side effect (may affect up to 1 in 1000 people):

- posterior reversible encephalopathy syndrome (neurological disturbance)

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enzalutamide	Once per day	Once per day	Once per day	Once per day	Once per day	Once per day	Once per day
AZD5363	Twice per day	Twice per day	Twice per day	Twice per day	none	none	none

Symptoms may include headache, seizures, altered consciousness and visual disturbance.

AZD5363

Most commonly reported side effects;

- Diarrhoea
- high blood sugar - please tell your doctor if you develop an excessive thirst or experience an increase in the number of times you need to go to the toilet (to pass urine)
- fatigue
- rash
- decreased appetite
- nausea and vomiting
- feeling short of breath
- inflammation (redness and swelling of the mouth and lips), managed with treatments such as mouth washes and steroid based creams.
- Itching, managed with anti-histamine or steroid skin creams.

Other reported side effects include;

- dry skin, managed with moisturizing creams
- hepatotoxicity (damage to the liver) – please tell your doctor if you experience a yellowing of your skin colour or eyes, itching of the skin or pain on the upper right side of your belly
- hypersensitivity: A very small number of patients (just over 1%) experienced hypersensitivity (allergic reactions) while taking AZD5363 that required admission to hospital or prolongation of existing hospital stay, with symptoms such as itchy rash, fever, hives, throat itchiness and swelling of the face. These developed either sometime after the initial administration of AZD5363 or soon after reintroduction of the drug following interruptions for other reasons. In each instance the reaction subsided and resolved once AZD5363 was stopped and other medication such as antihistamines were given. In most cases there have been other reasons that could also have caused the events, such as pre-existing allergy, and other medications given at the same time as AZD5363 that are known to cause hypersensitivity. We believe, based on evaluation of these and other events in patients receiving AZD5363, that there is reasonable possibility that AZD5363 causes hypersensitivity reactions in some patients. In extreme circumstances hypersensitivity reactions can be life-threatening or even fatal. Please keep your doctor informed if you experience any of the above symptoms when or soon after you start your treatment with AZD5363.

It is important to tell your doctor if your experience any of the side effects listed above or any other problems as soon as possible so they can advise you what to do.

Will there be anything extra I need to do if I take part in RE-AKT?

Yes, if you choose to take part in RE-AKT you will need to visit your hospital more often than you may otherwise need to and will have extra assessments to monitor your cancer and safety in the study. We will also ask that you provide blood, urine, saliva samples, a buccal (cheek) swab and samples of your cancer, known as biopsies during the study. There is currently no information available to help doctors to individually select the best treatment for people with your type of cancer. The samples you donate will help to provide this information for doctors to use in the future.

More information about what this will involve is in part 2 of this information sheet.

How many times will I need to visit the hospital?

You will be seen regularly by your study doctor/nurse after you join the study. Each visit will involve having medical investigations to check on the status of your health.

During cycle 1 we will take regular blood and hair samples to measure the levels of AZD5363 to see how much of the drug is in your blood and hair and to see the effect the drugs having on your body. 8 blood samples will be taken at different times over 3 days (just before you take the first dose of drug, and then 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 24 hours and 48 hours after you have taken the drug). We will collect approximately 2-12 ml or 1-2 teaspoons at each time point.

You will be asked to come to the hospital 10 times during the first 12 weeks of treatment. From 12 weeks (cycle 4) of treatment you will come every 4 weeks until the trial treatment is no longer helping to stop the growth of your cancer. When this happens, you will need to stop taking enzalutamide and AZD5363 and return to hospital 4 weeks later. After this your doctor will decide what is the best treatment for you. We won't ask you to have any more investigations for the RE-AKT study but would like to continue to collect information about how you are doing.

The Combination Treatment Schedule Table shows what will happen at each of your hospital visits.

On the days of your hospital visits you doctor may ask you to be fasted (not eaten anything for 8 hours overnight) and wait to take your morning study drugs until after you have had your blood tests. This is because some tests need to be taken before you eat anything and before or after you take your study drugs. It is extremely important that you take the study drugs exactly as your doctor tells you to.

What else do I have to do?

Before deciding to take part in this study, you need to consider carefully how these tests and hospital visits will affect you and your family. Some tests may be uncomfortable. Please ask your hospital doctor or nurse if you have any questions about the tests and procedures. If you decide to take part, you will need to:

- sign the study consent form to show you understand what RE-AKT involves
- attend all scheduled appointments
- take your trial treatment as directed
  - Enzalutamide once a day at approximately the same time each day. The capsules should be swallowed whole with water, and can be taken with or without food.
  - AZD5363 twice daily on an intermittent (4 days on and 3 days off) weekly dosing schedule. Tablets should be taken at approximately the same times each day on an empty stomach (do not eat for at least two hours before taking the tablets). You should then wait an hour after taking the tablets before you eat anything.
- store the medication in the bottle given to you by your study doctor or pharmacist as directed on the label.
- talk to your study doctor first if you want to stop taking the trial treatment for any reason
- only take the trial treatment yourself. Keep them out of the reach of children
- tell your doctor about any other medicines that you take, even if you buy them without a prescription. Before starting any new medication, including over the counter medications or herbal supplements, please check with your study doctor or nurse. Avoid any medications known to increase the chance of having a seizure (fit).
- tell your doctor about any medical problems you have
- avoid drinking large amounts of alcohol
- use an effective method of birth control to avoid fathering a child while on study treatment and for 12 months after the last dose of study drug. If this happens whilst you are taking study drug, you will need to tell your study doctor. Acceptable methods of birth control include condom plus spermicide in combination with a female condom, diaphragm, cervical cap or intrauterine device. If you need further information about effective methods of contraception for use whilst in RE-AKT, please talk to your doctor
- return your medicine containers (with any leftover tablets) to the study team at each visit
- women who are or may become pregnant (such as spouse or caregiver) should not handle enzalutamide capsules that have been damaged or broken without protection (such as gloves). In addition, to help prevent accidental exposure by others, please do not chew, dissolve, or open the capsules.

It is very important that you follow these requirements to continue safely in the study. You will also be given a card, which will provide details about the RE-AKT trial and that you are taking enzalutamide and AZD5363. Please carry it with

you at all times while you are taking part in this trial.

Combination treatment schedule ***Key:*** **= pre drug, 30mins, 1, 2, 4, & 8 hours post drug*	**Before you start treatment**	**On the day you start treatment (C1D1)**	**On the second day of treatment**	**On the third day of treatment (C1D3)**	**4 & 11 days after you start treatment (C1D4 & C1D11)**	**4 weeks after starting combination treatment (C2D1)**	**Cycle 2 Day 4**	**Cycle 2 Day 11**	**8 weeks after you start combination treatment (C3D1)**	**12 weeks after starting combination treatment and every 4 weeks after that**	**End of treatment**	**4 weeks after you stop treatment**
A physical examination including measurement of your heart rate blood pressure, height and weight.	**X**	**X**				**X**			**X**	**X**	**X**	**X**
Assessment of current symptoms and medications.	**X**	**X**		**D4**	**X**	**X**			**X**	**X**	**X**	**X**
Electrocardiogram (ECG) heart test	**X**											
ECHO / MUGA heart function test	**X**											
Blood tests (3-8 teaspoons)	**X**	**X**			**X**	**X**		**X**	**X**	**X**	**X**	**X**
CT and bone scan	**X**									**12 weekly**		**X**
Collection of your existing tissue sample or biopsy of your tumour for research.	**X**											
Biopsy from your prostate or from a site to which your cancer has spread	**X**				**D4 or D11**						**X (optional)**	
Urine sample collected over 24 hours for research	**X**	**X**				**X**				**X**	**X**	
Blood sample for research (7-27 teaspoons)	**X**	**X***			**X**	**X**	**X**	**X**	**X**	**X**	**X**	
Saliva and buccal swab for research	**X**											
Hair sample for research		**X**			**D4 or D11**	**X**	**X**					

How long will I need to take enzalutamide and AZD5363?

Study treatment will be stopped if your study doctor finds that it is no longer helping to control your disease, you are experiencing intolerable side effects or you no longer want to continue on the treatment.

What are the alternatives for treatment?

If you do not take part in this study, your doctor will discuss all alternatives with you and you will be offered the best available alternative treatment. You will not be offered this combination treatment outside the study.

4 What are the possible advantages and disadvantages of taking part?

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

AZD5363 is an unlicensed drug, which means that it is still experimental and not all of its side effects are yet known. You may therefore experience some side effects, which are not listed above. There is no way of predicting if you will experience any, or how severe they will be. You must contact your study doctor if you experience any side effects even if you are not sure that any problems you may have are related to the taking the tablets.

You will have more blood tests, urine samples and biopsies in RE-AKT than if you were not in the study. Risks linked with blood sampling include pain from the needle being inserted, light-headedness, possible fainting and (rarely) infection. Possible risks, discomfort or inconveniences associated with the collection of biopsies will depend upon the type of biopsy performed. The taking of a biopsy may cause some pain, redness, swelling, slight bruising at the biopsy site and rarely fainting. There is a small risk of bleeding, infection, wound healing problems following your biopsy.

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.

An ECHO is an ultrasound scan and involves placing a microphone-like probe on the skin of your chest to get images of your heart and assess its function. Alternatively, A MUGA scan can be performed to assess your heart function; it is a different test that produces images of your heart using a small amount of radioactive solution injected into your vein.

If you take part in this study you will have a CT scan (uses special x-ray equipment to take pictures of the inside of your body to assess the extent of your cancer) and a bone scan before you start and then every three months afterwards (5 times in a year). Some of the biopsies many be carried out under CT guidance. You will also have a MUGA or an ECHO scan before you start treatment. CT scans, bone scans, MUGA scans and CT guided biopsies all use ionising radiation (either x-rays, or from radioactivity) which can cause cell damage that may, after many years or decades, turn cancerous. However, for people taking part in RE-AKT the risk of this affecting them is very small.

Having five CT and bone scans, CT guided biopsies and a MUGA scan will expose you to an amount of radiation comparable to 66 years' worth of normal background radiation in the UK. Radiation can cause cell damage which may in the long term be harmful. However in view of your clinical condition the radiation exposure is not significant and the risk of long- term harm is considered to be negligible.

You will need to attend hospital more frequently than you would if you were receiving standard care. 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 and your doctor will discuss this with you.

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

What are the possible benefits of taking part?

Your doctors think that the combination of enzalutamide and AZD5363 might help to control your cancer, but we cannot guarantee it. The information we gain from this study may help us to improve treatments for patients with advanced prostate cancer in the future.

What happens when the research study stops?

RE-AKT will continue until everyone who is participating has stopped taking study drug. When you stop taking study drug your doctor will discuss with you your next options for treatment.

What if relevant new information becomes available?

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

If new information means it would be in your best interests to withdraw you from the study, your doctor will explain the reasons and arrange for your continued care.

If the study is stopped for any other reason, you will be told why and your study doctor will arrange for your continued care.

What happens if I don't want to carry on with the study?

You are free to withdraw from RE-AKT at any time. You do not have to give a reason and your future treatment will not be affected. Your doctor will discuss your treatment options with you and will offer the most suitable treatment available. However, if you were to withdraw, we would like your permission to keep the information and samples we have already collected from you and to continue to collect information on your progress that is routinely recorded in your medical records. If you decide to withdraw completely and don't want us to use anything we have collected so far, you must inform your study doctor who will ensure that all data and any stored samples are destroyed.

What if something goes wrong?

Every care will be taken in the course of this clinical trial. If you are not happy with the general care and treatment you receive during the study, please speak first to your study doctor, who will try to resolve the problem. If you remain unhappy and wish to complain formally about the care and treatment received during the study, you may do so under the standard NHS complaints procedure which is available to you from your study doctor's hospital.

If you suffer any side effects or injury, please notify the study 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 for compensation. 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 medication 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. 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.

Will my taking part in this study be kept confidential?

All information which is collected about you during the research will be kept strictly confidential. When you join the study, your name, date of birth, postcode, hospital number and NHS or Community Health Index (CHI) number will be passed to the Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) where the study is being coordinated. You will be given a unique trial number, which will be used together with your initials and date of birth on forms that the research staff will give to ICR-CTSU. All information about you will be coded with the trial number and 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 team will have access to the information that could allow this study number to be linked to you.

Members of the research team, including ICR-CTSU staff, sponsor representatives, regulatory authority employees and representatives from the NHS Trust relevant to your taking part in research may need to examine your medical records to ensure the study is being run properly and that the information collected on the forms is correct. However, your confidentiality will be protected at all times.

The research team will be contacting your hospital from time to time to find out how you are getting on. Ideally this will happen for life, but patients sometimes change address and/or GP or lose touch with their hospital. If this happens the research team at ICR-CTSU 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). Any details received from any source are confidential and will only be used for the purposes of the trial. Please initial the consent form to show that you agree for this to happen.

You will retain the right to ask to be shown all your personal data that has been collected for this study, and if you think anything is incorrect you may ask to have it corrected.

All the information that is sent to ICR-CTSU will be kept for up to 20 years after the RE-AKT study has ended. [*Insert appropriate name for local NHS site*] will keep your information in line with their local policies but no longer than 20 years after the study has ended.

Will information about me be shared with other researchers?

The organisers of this study would like to be able to combine information collected about patients in this study with information collected for other studies, if in the future it is a useful way of advancing our knowledge of the treatment of cancer. If this happens, information about you may be passed to other researchers, but they would not be able to identify you from the information provided.

5 Further information about taking part

Involvement of your General Practitioner/Family doctor

Your General Practitioner (GP) will be informed about your participation in the study. This will ensure that your GP knows you are taking enzalutamide and AZD5363 in the event of any potential side effects and/or drug interactions.

What will happen to the results of the research study?

Independent experts will review the progress of the research and the results will be published in a medical or scientific journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how to treat prostate cancer in the future.

Who is organising and funding the research?

The research study is being organised by The Royal Marsden NHS Foundation Trust (Chief Investigator Professor Johann de Bono) and The Institute of Cancer Research. It is being coordinated by The Clinical Trials and Statistics Unit at the Institute of Cancer Research and has been endorsed by Cancer Research UK. AstraZeneca UK Limited, who make AZD5363, are supplying the study drug for free and are also providing funding for RE-AKT. Astellas Pharma, who make enzalutamide, are supplying the drug for free. The funding helps to cover the cost of including you in the study, the laboratory tests and helps support the study staff. None of the researchers are personally benefiting from the trial funding.

Will I get travel costs?

You can claim up to £60 per visit towards the cost of travel for yourself to attend each study visit. Your doctor or nurse will let you know how to claim this.

Who has reviewed the study?

Cancer Research UK have reviewed RE-AKT and supports the aims of the study. RE-AKT has also been approved by the London-Surrey Borders Research Ethics Committee. 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.

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 join the RE-AKT study you will be asked to sign a consent form and will be given a copy to keep together with this information sheet.

Part 2 - Looking at biological samples collected for research

6 What sort of samples will I be asked to donate?

If you agree to join RE-AKT you will be asked to donate blood, urine, saliva and samples of your cancer. Providing all these samples is an important part of the study.

- **Blood**

The bloods will be collected when you register for the study, on the day you start AZD5363 treatment, after four weeks of combination treatment and every 4 weeks after this and again when you stop treatment. Your doctor or nurse will take between 32mls and 51mls, which is about 7-12 teaspoons full, each time. You will also have regular blood samples taken during cycle 1 as described on page 8.

- **Tissue**

A sample of your cancer will be collected before you start taking treatment and again during the first cycle of combination treatment. It is necessary to provide these samples in order for you to be able to take part. The section below 'What does having a biopsy involve?' gives you more information about having a biopsy.

- **Urine**

The urine will be collected when you register for the study, on the day you start AZD5363 treatment, after four and 12 weeks of combination treatment and again when you stop treatment. The sample will be all the urine produced in the 24 hour period preceding your hospital visit.

- **Buccal (cheek) Swab**

A swab of the cells of the inside of your cheek will be collected before you start treatment.

- **Saliva Collection**

You will be asked to spit into a container several times to collect saliva before you start treatment.

- **Hair**

Approximately 5 hair follicles will be collected from either your eyebrow or scalp at each time point.

What does having a biopsy involve?

A biopsy is the removal of a small piece of tissue from the tumour using a special needle. The sample may be taken from the prostate itself or from another site where there is evidence of cancer. In most cases the biopsy will be performed as a day case. The doctor taking the biopsy will use a machine to see where the tumour is, either an ultrasound or a CT scan. You will have a local anaesthetic first to numb the area. You may experience some mild pain, bruising or soreness as a result of the biopsy. Painkillers will be prescribed for you to take home with you if required. There is a very small risk of infection or of bleeding at the site of biopsy and an even smaller risk of damage to other organs of the body that lie close to the entry path of the biopsy needle.

What will happen to any samples I give?

All samples collected as part of the RE-AKT study will be sent to a research laboratory at The Institute of Cancer Research (ICR) where they will be stored securely.

Expert scientists, working together with the RE-AKT study team, will look at the samples you provide. The research team hope to find biological markers that may help to predict

how well enzalutamide and AZD5363 treatment will work for individuals and also find out more about your type of cancer. This will involve looking at the genetic information in the samples collected from you and at any changes in response to treatment. You will not be provided with information from any of the tests conducted on your samples.

There is currently no information available to help doctors to individually select the best treatment for people with your type of cancer. The samples you donate will help to provide this information for doctors to use in the future. The research team may in the future share the information gained from the samples you provide, including genetic details, with other researchers investigating this type of cancer. You will not be identifiable from this information. Please initial the consent form if you are happy for this information to be shared.

If you give your permission, after the RE-AKT study is complete, your samples will be stored for use in future studies. Any research using your samples will have approval from a Research Ethics Committee.

What information about me will be sent with my samples?

The samples you donate as part of RE-AKT will be labelled with your trial number, initials and date of birth. This will maintain your confidentiality whilst allowing biological information to be compared to how well enzalutamide and AZD5363 treatment works for you.

7 Transparency statement

The Institute of Cancer Research and the Royal Marsden are the co-sponsors for this study based in the United Kingdom. The Institute of Cancer Research will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. 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 study has finished, in line with local policies and legal requirements.

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 study, 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. [*Insert appropriate name for local NHS site*] will collect information from you and/or your medical records for this research study in accordance with our instructions. [*Insert appropriate name for local 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 study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

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. 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.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-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.

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

and 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 GDPR or how we use your information please contact our Data Protection Officer at dataprotectionofficer@icr.ac.uk

8 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. They have published useful information about (1) prostate cancer (2) individual treatments and (3) clinical trials in general. You can contact one of their specialist cancer nurses on their freephone number, 0808 808 00 00 or look on their internet website: (http://www.macmillan.org.uk/Home.aspx).

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/). Other useful websites on prostate cancer treatment and trials are the Prostate Cancer UK and Prostate Cancer Foundation websites:

http://prostatecanceruk.org
http://www.pcf.org

Thank you for your interest in our research.

Your specialist is: _____

Contact phone numbers:

_____