

## SoFEA

### **Study of Faslodex with or without concomitant Arimidex vs Exemestane following progression on non-steroidal Aromatase inhibitors**

#### **BIOLOGICAL STUDIES**

#### **Use of your Tissue and Blood Samples for Medical Research**

#### **PATIENT INFORMATION SHEET**

##### **What is the purpose of this study?**

As part of our research, we want to understand more about why some patients respond better to hormone treatment than others. To help us to do this we are planning to conduct some laboratory research using some tissue from your tumour, and from some of your blood. Some tests can be done straight away, and some tissue can be stored and used for research into cancer in the future.

##### **What tumour tissue is needed for this research?**

When your breast cancer was first diagnosed, samples of the cancer tumour were stored in the pathology department of your hospital. We would like to ask your permission to use this tissue to test for biological markers within the tumour cells that might tell us which patients respond best to which hormone treatments.

##### **What additional tissue sample is required?**

For some patients, secondary breast cancer appears in a place where it is fairly straightforward for doctors to take a small sample without causing unnecessary distress or inconvenience. If this has happened with you, we would like to take a small biopsy or needle test of some of the secondary breast cancer before you begin study treatment. This sample will be used to test for the same biological markers as your primary tumour. It can then be stored so that we can carry out more laboratory research into cancer in the future.

##### **What blood samples are required?**

If you agree, we would like to take some blood samples for research on 2 separate occasions. On each occasion, we wish to take about 9mls of blood (approximately 2 teaspoons). The first sample should be taken while you are continuing on your current tablets (Arimidex or Femara) and before you begin your new treatment. The second sample will be taken at approximately 12 weeks from the start of study treatment. These samples will be used to measure the female hormone levels in your blood.

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

No. You can still take part in the main part of the SoFEA study without taking part in the biological studies. You can also take part in some but not all of the biological studies. For example, if you would like to donate tissue from your original cancer tumour, but do not want to donate tissue from your secondary breast cancer, you can do this.

##### **Will taking part affect my care?**

No. The results from tests on your tumour or blood samples will not provide your doctor with information that will tell him/her which hormone treatment is best for you.

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

If you agree to take part in the biological studies you may be asked to have a small biopsy sample taken of your secondary breast cancer (under local anaesthetic) before your treatment starts. This will mean an additional out-patient visit or a day case admission. The surgery may cause a small amount of discomfort and some minor bleeding.

### **Who will test the tissue and blood samples?**

Your tumour and blood samples will be sent for testing to specialist laboratories at The Royal Marsden NHS Foundation Trust / The Institute of Cancer Research in London.

### **What will happen to the samples?**

Small pieces will be taken from the tumour samples when they are received at the specialist laboratory and the remainder will be returned to the pathology department at your hospital.

Tissue and blood samples will be stored under the custodianship of The Royal Marsden NHS Foundation Trust / The Institute of Cancer Research, for future research. Some of the left over blood will be thrown away.

### **Will I find out the results of the research using my tissue?**

No. We need to test tumour and blood samples from many different patients before we have any results. Some samples are stored for research in the future.

### **Will I benefit from the research using my tissue or blood samples?**

No, there will be no direct benefit to you, but the results of this research could provide valuable information that helps patients in the future.

### **How will my samples be collected and sent to the researchers?**

Researchers at The Institute of Cancer Research or the ISD Cancer Clinical Trials Team (Scotland) will ask the hospital pathologist responsible for looking after your tumour samples to send them to the specialist laboratory at The Royal Marsden NHS Foundation Trust. Your blood samples will be taken by a nurse in clinic who will arrange for them to be sent to The Royal Marsden NHS Foundation Trust. Your tumour samples will be identified by your initials, unique study number, and date of birth.

### **How is confidentiality protected?**

Information about you is kept private, and careful steps are taken to make sure personal records are not misused. Your hospital will only pass information linking you to your tumour or blood samples to authorised researchers at The Institute of Cancer Research and ISD Cancer Clinical Trials Team (Scotland). These authorised researchers are the only people who can link you to the results of laboratory tests carried out on your tumour and blood samples.

Your doctor or nurse will be happy to answer any questions you have about this study. You can telephone them, or speak to the doctor again when you come to the clinic.

Thank you for taking the time to read this information sheet  
and for considering taking part in these important biological studies.