
THE IRESSA[®] ACCESS PROGRAM PATIENT CONSENT FORM

Introduction

Additional information about IRESSA[®] (gefitinib tablets) has recently become available. As a result of that information, the IRESSA Access Program is being implemented effective September 15, 2005. The IRESSA Access Program places limitations on the types of patients who can take IRESSA and the way qualifying patients can receive their supply of IRESSA.

You may be eligible to obtain IRESSA through the IRESSA Access Program. For you to be able to decide whether you want to sign up for the IRESSA Access Program, you should understand enough about the risks and benefits of IRESSA therapy to make an informed decision. This process is known as informed consent. Once you have been informed and have had any questions you may have about IRESSA answered, you will be asked to sign this consent form if you wish to receive IRESSA through the IRESSA Access Program. You do not have to sign this consent form. If you do not sign this consent form, you will not be able to receive IRESSA after September 15, 2005.

Read this information carefully and please ask your doctor or his/her staff if you have any questions about IRESSA at any time.

Important Facts about IRESSA and the IRESSA Access Program

In May 2003, the Food and Drug Administration (FDA) granted accelerated approval to IRESSA as a prescription medicine for the treatment of patients with locally advanced (cancer that has spread within the lungs or chest) or metastatic (cancer that has spread to other parts of the body outside of the lungs) non-small cell lung cancer (NSCLC) after they have received treatment with both platinum-based and docetaxel (Taxotere) chemotherapies, and those treatments have failed. IRESSA was approved on the basis of tumor shrinkage in about 10% of the patients who took it in the IDEAL clinical trial.

In December 2004, the FDA reviewed the results of a recently completed clinical trial comparing IRESSA to placebo (sugar pill). The trial showed that, overall, patients taking IRESSA did not live significantly longer than patients taking placebo. Based on the results of this trial and after discussions with the FDA the Prescribing Information for IRESSA has been changed, so that IRESSA is now approved for use only for the continued treatment of patients who are benefiting or have benefited from IRESSA. IRESSA is also available through the IRESSA Access Program for patients who are enrolled in or will be enrolled in clinical trials approved by an Institutional Review Board (IRB) prior to June 17, 2005.

The IRESSA Access Program has been set up to make sure that patients who have received and benefited from IRESSA before September 15, 2005, and patients in clinical trials with IRB approval prior to June 17, 2005 will have the continued option of receiving IRESSA after that date. For qualifying patients choosing to enroll in this program, IRESSA will be supplied through a single mail-order pharmacy, Priority Healthcare.

If you have received IRESSA as treatment and you and your doctor have determined that you are benefiting or have benefited from IRESSA, or if you are a subject in a qualifying clinical trial of IRESSA, you may be eligible to receive IRESSA through the IRESSA Access Program after September 15, 2005. You must sign this consent form and your doctor must sign a separate form. Your doctor must then send both completed forms and a prescription for IRESSA to Priority Healthcare. Priority Healthcare will mail your supply of IRESSA to the address you designate. Priority Healthcare will also send you information on how to refill your prescription. If you have any questions about the IRESSA Access Program, you can call 1-800-601-8933 to speak to a representative.

If you decide to enroll in the IRESSA Access Program, you are still free to stop taking IRESSA at any time, for any reason. If you do not want to continue IRESSA treatment or participate in a clinical trial of IRESSA, there are other treatments for your disease which are available to you. Your doctor can discuss these options in detail with you.

IRESSA Clinical Studies

Clinical information about IRESSA that you need to be aware of includes final survival data from three randomized controlled trials in which IRESSA was compared to placebo, and preliminary data from another clinical trial which was stopped earlier than planned.

Two studies in patients with newly diagnosed advanced (stage III and IV) non-small cell lung cancer found that IRESSA did not provide any additional survival or other benefit when given together with commonly used chemotherapy drugs in NSCLC subjects.

In another large study called ISEL (IRESSA Survival Evaluation in Lung Cancer), conducted after IRESSA received accelerated approval by the FDA, IRESSA was tested to see if it was significantly better than placebo (sugar pill) in prolonging survival in patients with recurrent (cancer that returned after treatment) advanced lung cancer who had been previously treated with chemotherapy. Overall, patients taking IRESSA did not live significantly longer than patients taking placebo.

Another trial was designed to test whether giving IRESSA to newly diagnosed advanced (stage III) non-small cell lung cancer patients who had successfully completed chemoradiation therapy was able to improve survival compared to placebo (SWOG 0023). Early data appeared to show that even if the study continued, it would not be likely to show that IRESSA improved survival, and the trial was stopped.

Alternative Treatments

Another oral drug, called erlotinib (Tarceva[®]), that acts like IRESSA on tumor cells, was also compared to placebo in a large randomized trial in patients with recurrent non-small cell lung cancer. Patients taking Tarceva in that trial lived significantly longer than patients taking placebo. Tarceva has been approved for treatment of patients with NSCLC with recurrent disease and is available without limited distribution. A chemotherapy drug, docetaxel (Taxotere[®]), has also been shown to improve survival in recurrent non-small cell lung cancer patients when compared to placebo. Other chemotherapy agents have been shown to shrink tumors in these same cancer patients. You are urged to discuss these alternative treatments and other treatment options with your doctor, so that you and your doctor can decide whether IRESSA or another treatment is best for you at this time.

Description of IRESSA Treatment

If you choose to receive IRESSA through the IRESSA Access Program, your care will continue to be directed by your physician. No additional laboratory tests or procedures are required. As before, your physician will manage any problems or needs you have. You may stay on IRESSA until you and your doctor determine that you should stop taking it.

For more information about IRESSA treatment, ask your doctor about the full IRESSA Prescribing Information and discuss it with him or her. The IRESSA Prescribing Information can be obtained by calling AstraZeneca at 1-800-601-8933 or visiting the web at www.iressa-access.com.

Possible Benefit of IRESSA Therapy

If you have received and benefited from IRESSA before September 15, 2005, the possible benefit to you is that whatever benefit you have received from IRESSA may continue for a period of time. The duration of this time is unknown. It is also unknown if you would get the same or perhaps an even greater benefit from other therapy.

If you are a participant in a qualifying clinical trial of IRESSA, your doctor will review with you the possible benefit of receiving IRESSA through the trial.

Taking IRESSA is Voluntary

It is up to you and your doctor whether you continue to take IRESSA if you have previously benefited from IRESSA. Likewise, it is up to you and your doctor whether you participate in an approved clinical trial of IRESSA.

Confidentiality and Authorization to Collect, Use and Disclose Your Medical Information

What Does Medical Information Mean?

Your medical information is information about your physical or mental health or condition. This information may identify you because it may contain, for example, your name, address, telephone number, photograph, date of birth, social security number, race or ethnic origin or other unique identifiers. It includes:

- your previous medical records; and
- information about you that is created or collected by any physician, hospital or other healthcare provider that treats you.

Use and Disclosure of Your Medical Information

By signing this consent form, you allow your doctor to share your medical information with:

- AstraZeneca Pharmaceuticals LP, the manufacturer of IRESSA, including its affiliates, representatives and contractors who work on its behalf;
- Priority Healthcare, including its affiliates, representatives and contractors who work on its behalf;
- other doctors and health care professionals; and
- the Food and Drug Administration.

If you sign this form, you also authorize any physician, hospital or other healthcare provider that treats you with IRESSA to disclose to your doctor any medical information about you that he/she may need in order to be able to monitor and/or report to regulatory authorities on the safety of IRESSA.

Notice on Redisclosure of Your Medical Information and Confidentiality

Federal law provides that your doctor can only share your medical information with those persons whom you have permitted to see it. However, if you sign this form, those persons may share your medical information with other persons. Federal law does not protect you against this. (The laws of your state may provide additional privacy protection.)

THE IRESSA[®] ACCESS PROGRAM PATIENT CONSENT FORM

I HAVE REVIEWED AND I UNDERSTAND ALL THE INFORMATION IN THIS PATIENT CONSENT FORM. I HAVE BEEN GIVEN THE CHANCE TO DISCUSS IT WITH MY DOCTOR AND ASK QUESTIONS. ALL MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. I VOLUNTARILY CONSENT TO TAKE IRESSA, AND I UNDERSTAND THAT I WILL RECEIVE IRESSA ONLY THROUGH THE IRESSA ACCESS PROGRAM AFTER SEPTEMBER 15, 2005. I AUTHORIZE THE COLLECTION, USE AND DISCLOSURE OF MY MEDICAL INFORMATION IN ACCORDANCE WITH THIS FORM.

Signature of Patient

Date of Signature

Printed Name of Patient

I REQUEST PRIORITY HEALTHCARE TO MAIL MY SUPPLY OF IRESSA TO THE FOLLOWING ADDRESS:

Signature of Person Administering this Consent

Date of Signature

Printed Name of Person Administering this Consent

*Patient: Please keep a complete copy of this fully executed form and give your physician the original.
Physician: Please retain this original executed form with the original executed Physician Certification Form for this patient in your files. Submit copies of both forms with a prescription for IRESSA to Priority Healthcare by fax to 1-888-792-9831 or by mail to: Priority Healthcare, 250 Technology Park, Lake Mary, FL 32746 ATTN: IRESSA ACCESS PROGRAM. Priority Healthcare will fill the prescription on or after September 15, 2005.*

(The legally acceptable representative signature should be added if the patient is unable to sign for him or herself, or if the patient is under 18 years of age. The relationship between the patient and the legally acceptable representative should be stated. The impartial witness signature should be added if the patient is unable to read or write).

Signature of Legally Acceptable Representative

Date of Signature

Printed Name of Legally Acceptable Representative

Relationship of Legally Acceptable Representative to Patient

Signature of Impartial Witness

Date of Signature

Printed Name of Impartial Witness

*Patient: Please keep a complete copy of this fully executed form and give your physician the original.
Physician: Please retain this original executed form with the original executed Physician Certification Form for this patient in your files. Submit copies of both forms with a prescription for IRESSA to Priority Healthcare by fax to 1-888-792-9831 or by mail to: Priority Healthcare, 250 Technology Park, Lake Mary, FL 32746 ATTN: IRESSA ACCESS PROGRAM. Priority Healthcare will fill the prescription on or after September 15, 2005.*