



Consent For Erlotinib (Tarceva®) and Bevacizumab (Avastin®)

Condition For Which Treatment is Proposed: _____

1. I hereby authorize my physician, Dr _____, and/or such other staff physicians or resident physicians as my physician may designate, to administer to me (or the patient for whom I consent) the following treatment consisting of:

1. Erlotinib (Tarceva®)
2. Bevacizumab (Avastin®)

The plan for my course of treatment is for _____ cycles of therapy, with each cycle given about every _____ days.

2. My physician has discussed with me the items that are briefly summarized below:

(1) The nature and purpose of the proposed therapy is to administer therapy (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein or by other type of injection.

(2) You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer therapy). The discomfort associated with venipuncture is a slight pinch or pinprick when the sterile needle enters the skin. The risks of venipuncture include mild discomfort and/or a black or blue mark at the site of the needle puncture. Less commonly, a small blood clot, infection or bleeding may occur at the needle puncture site. When therapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the therapy leaking outside of the vein causing tissue irritation or damage.

(3) It is unknown what effects this therapy may have on an unborn child in a pregnant woman. It is known that there is an increased risk for ovarian failure in patients receiving Avastin. Ovarian failure may not be reversible upon discontinuation of therapy. For pregnant women, it is expected that there would be harm to the unborn child with this therapy. Please notify your doctor if you think you may be pregnant. It is important that both men and women who are being treated with these therapies and who are sexually active, fertile, and who have a fertile partner use a reliable form of birth control (birth control pills, a reliable barrier method or a hormonal implant.)

The drugs which will be used for my planned treatment and their specific side-effects:

Erlotinib (Tarceva®):

Most Common (>10%):

- Rash, itching, dry skin
- Diarrhea
- Nausea/vomiting, decreased appetite
- Pancreatitis (belly pain)
- Mouth sores



- Conjunctivitis
- Irritation to the liver
- Shortness of breath or cough
- Increased risk of infection

Less Common (1-10%):

- Acne
- Weight loss
- Pneumonitis (inflammation of the lung tissue)
- Pulmonary fibrosis (scarring of the lung)
- Abnormal liver function (determined by blood test that measures liver enzymes)
- Severe skin rash- skin peeling

Rare but serious (<1%)

- Acute kidney failure
- Liver failure
- Hearing Loss
- Bleeding in the gastrointestinal tract

Bevacizumab (Avastin ®):

Most Common (>10%)

- High blood pressure
- Low blood pressure
- An increased risk for blood clots than if receiving chemotherapy alone
- At risk for anticoagulation therapy to be ineffective for blood clot prevention
- Headache/pain
- Dizziness
- Fatigue
- Hair loss
- Dry and/or peeling of skin
- Bleeding (usually minor) such as a nosebleed
- If currently taking an anticoagulant your risk of bleeding is increased vs people who are not taking an anticoagulant.
- Allergic reaction and possible fever, chills, or shakes during the infusion
- Nausea/Vomiting/taste changes/loss of appetite
- Constipation/Diarrhea
- Increased risk of infection

Less Common (1-10%)

- Altered kidney function (determined by blood test)
- Abnormal salt blood levels or protein in the urine
- Abnormal liver function (determined by blood test that measures liver enzymes)

Rare but serious (<1%)

- Changes to the brain that can include: headache- associated with seizure, confusion, tiredness, blindness
- Gastrointestinal Perforation (hole in gastrointestinal tract)
- Stroke
- Hemorrhage



- Ovarian failure
- Osteonecrosis of the jaw

- The medically reasonable alternative treatments and the risks associated with these alternative treatments have been described by my physician. These alternatives include no treatment, combinations of different therapy drugs, or the same drugs given in different doses or on a different schedule.
- Without the proposed treatment, my disease may progress; it could remain stable or, rarely, improve.
- I understand that during the course of this treatment, unforeseen conditions may arise which could require the planned treatment to be altered. All alterations to the planned treatment will be discussed with me.
- I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the proposed therapy.
- I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the treatment described above. I have had the opportunity to ask questions concerning my condition, the treatment, the alternatives and risks, and all questions have been answered to my satisfaction.
- I impose the following limitation(s) regarding my treatment (if none, so state): _____

- I authorize the staff of The Milton S. Hershey Medical Center to preserve for scientific or teaching purposes any tissues or parts which may be removed in the course of this procedure, and to dispose of them.
- I authorize the Milton S. Hershey Medical Center to permit other persons to observe this therapy with the understanding that such observation is for the purpose of advancing medical knowledge. I authorize The Milton S. Hershey Medical Center to obtain photographic or other pictorial representations of this therapy, and to use such representations for scientific or teaching purposes.
- I certify that all blanks requiring insertion of information were completed before I signed this consent form.

_____ provided the information summarized above and obtained the
(Fill in name) consent for the procedure

_____/_____/_____
(Patient's Signature) (Date) (Time)
(or signature of person consenting on behalf of the patient)

_____/_____/_____



(Optional: Witness to Patient's Signature)

(Date)

(Time)

(Physician's Signature)

(Date)