PENNSTATE HERSHEY
Cancer Institute

Consent for **Ofatumumab**

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 therapy consisting of:

   Ofatumumab

   The plan for my course of therapy is for _____doses of Ofatumumab, with each dose given about every_____days.

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

   a. 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 vein.

   b. The risks of the proposed therapy:

   You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer chemotherapy). 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 chemotherapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the chemotherapy leaking outside the vein.

   It is unknown what effects this therapy may have on an unborn child in a pregnant woman, or any impact on your ability to have children in the future. 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 specific side-effects of Ofatumumab are:

Likely reactions:

Infusion Reactions: (44% of patients get some form of these reactions during the first infusion, 29% during the second infusion): These include asthma (wheezing), shortness of breath, edema of the larynx (voice box) swelling, fluid accumulation in the lungs, , flushing, high blood pressure, low blood pressure, fainting, angina, heart attacks, back pain, abdominal pain, fever, rash, hives have been reported. The infusion reactions are seen more with the first two infusions.

Reactions which occur in more than 10% of patients treated

Serious adverse reactions include low white blood cell (which can increase the risk of infection) and other blood cell counts (which may require transfusions), pneumonia (12% of which were fatal), fever, cough, diarrhea, fatigue, shortness of breath, skin rash, nausea, bronchitis and upper respiratory tract infections

Reactions which occur in fewer than 10% of patients treated

High blood pressure, low blood pressure, swelling of the ankles, rapid heartbeat, sweating, Hypotension, hives, Shingles (Herpes zoster) a serious infection with organ injury (sepsis) backache, muscular spasm headache, sleeplessness, shivering

Possible reactions (reactions which might occur, but have not yet been seen in patients

Progressive multifocal leukoencephalopathy (PML): Reactivation of a virus in the brain causing brain damage could occur and could be fatal.

Hepatitis B Reactivation: Reactivation of the hepatitis virus could occur, and could cause fatal liver injury. Patients will often have blood tests to check for this viral infection

Gastrointestinal: Obstruction of the small intestine can occur in patients with Ofatumumab therapy. Perform a diagnostic evaluation if obstruction is suspected.

Other considerations

3. 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 chemotherapy drugs, or the same drugs given in different doses or on a different schedule.

4. Without the proposed treatment, my disease may progress, it could remain stable or, rarely, improve.

5. I understand that during the course of this chemotherapy, unforeseen conditions may arise which could require the planned chemotherapy to be altered. All alterations to the planned chemotherapy will be discussed with me.

6. 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.

7. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the chemotherapy described above. I have had the opportunity to ask questions concerning my condition, the chemotherapy, the alternatives and risks, and all questions have been answered to my satisfaction.

8. I impose the following limitation(s) regarding my treatment (if none, so state):_____
_____

9. 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.

10. 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.

11. 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

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

_____/_____/_____AM/PM
(Optional: Witness to Patient's Signature) (Date) (Time)

_____/_____/_____AM/PM
(Physician's Signature) (Date) (Time)