PENNSTATE HERSHEY Cancer Institute

Consent for Regorafenib (Stivarga®)

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:

   Regorafenib

   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.

   (2) 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 this 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.

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

Regorafenib

Most common (>10%):

- Fatigue
- Decreased appetite/food intake
- Hand-foot skin reaction
- Diarrhea
- Mucositis
- Weight Loss
- Infections

- High Blood Pressure
- Voice alterations/hoarseness
- Headache
- Low blood counts (white cells to fight infection, red blood cells to carry oxygen, platelets to stop bleeding)
- Decreased blood electrolytes (calcium, potassium, sodium, and phosphorus)
- Increased liver enzyme function tests
- Increased protein in urine

Less common (1-10%):

- Liver failure
- Bleeding
- Heart attack (myocardial ischemia)
- Fistula formation
- Delay in wound healing
- Changes in taste, dry mouth
- Hair loss
- Muscle stiffness
- Tremor
- Low thyroid function tests

Rare, but serious (<1%)

- Bowel perforation (hole in the bowel) or fistula formation
- Other neurologic changes in addition to a severe headache (seizure, confusion, tiredness, blindness, or other changes) - a condition called reversible posterior leukoencephalopathy (RPLS)

An increased risk of infection has been noted when combined with chemotherapy.

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 therapy 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 treatment, unforeseen conditions may arise which could require the planned therapy to be altered. All alterations to the planned therapy 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 therapy, 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

_____/_____/_____
(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)