Patient Agreement to Systemic Therapy: Consent Form

Regorafenib

Patient's details / addressograph:	☐ Male ☐ Female
	Special requirements (e.g. other language/other communication method)
	Consultant:

Name of proposed course of treatment:

Regorafenib
Regorafenib taken by mouth once daily for 21 days, then 7 days rest
Treatment continued at the discretion of the treating doctor

Macmillan leaflet given ☐

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

☐ I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, follow-up appointments) and location.

The intended benefits

☐ Curative – to give you the best possible chance of being cured
☐ Palliative – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival
☐ Adjuvant – therapy given after surgery to reduce the risk of recurrence of cancer
☐ Neo-adjuvant – therapy given to shrink the cancer before surgery or radiotherapy

Significant, unavoidable or frequently occurring risks:

Common side-effects: hand/foot skin reaction (redness of the palms of your hands or soles of your feet, sore or swollen hands or feet), changes to the liver, effects on the skin (rash, redness, dryness or itching), high blood pressure, tiredness and feeling weak, diarrhoea, sore mouth and ulcers, feeling sick (nausea) and being sick (vomiting), loss of appetite, unusual bleeding and bruising (for example, your gums may bleed or you may notice blood in your urine), hair thinning, headache, reduced resistance to infection.

Less common but potentially life threatening side-effects: severe liver damage; gastro-intestinal perforation; severe bleeding (haemorrhage)

Other less common side-effects include: increased risk of chest pain (angina) or a heart attack; hoarseness or husky voice.

Rare cases of reversible encephalopathy with seizures, headache, altered mental status and visual disturbances have been reported.

Regorafenib may have an effect on fertility.

☐ I have warned the patient that there is an unknown risk of regorafenib affecting fertility (in men and in women)

Regorafenib may damage the development of a baby in the womb (fetus), leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women. The patient has been advised not to become pregnant / not to get a partner pregnant during the period of treatment and up to 8 weeks after treatment stopped.

Any other risks:

……

……

Clinician Signature

Signed…… Date ……

Full Name (print) ……..…. / …… Job Title……...
(Forename) (Surname)

Statement of patient

Patient Signature

Please read this form carefully, which describes the benefits and risks of the proposed treatment. You have the right to change your mind at any time, including after you have signed this form.

I agree to undergo chemotherapy. I understand the treatment and am aware of the potential side-effects arising from this treatment.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.

Signed…… Name……..……..

Date…….....

A witness should sign below if the patient is unable to sign but has indicated his or her consent.

Signature …… Date ……..……

Name (PRINT) ……..……

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ……..…… Date ……..…….

Name (PRINT) ……..……

Copy accepted by patient: yes/no (please ring)

Copy to be retained in patient's notes