Patient Agreement to Systemic Therapy: Consent Form

Pembrolizumab

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

Name of proposed course of treatment: Pembrolizumab

Pembrolizumab IV infusion on day 1
Repeated every 3 weeks
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: diarrhoea, nausea (feeling sick), itch, rash, joint pains, fatigue (feeling tired)

Less common but potentially life threatening side-effects: the development of auto-immune disease. This can cause various symptoms within the stomach and intestines (stomach pain or diarrhoea), impaired or altered liver function, severe skin rash, symptoms affecting the nervous system (pins and needles or numbness of fingers and feet, muscle weakness) or other organs (lungs, pancreas, kidneys, heart, eyes, hormone producing glands). It is important that any side-effects are treated when they occur, and before they get worse, as in severe cases the auto-immune diseases induced by pembrolizumab can be life threatening.

Other less common side-effects include: allergic reaction to the infusion

Pembrolizumab may damage the development of a 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.

Any other risks:
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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 ……..……..… Name (PRINT) ……..……..…… Date……

Confirmation of consent **(to be completed by the chemotherapy nurse when the patient attends for the first cycle)**
On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the treatment to go ahead.

Signed ……..……..… Name (PRINT) ……..……..…… Date……

Copy accepted by patient: yes/no (please ring)
Copy to be retained in patient's notes