

| Patient Agreement to Systemic Therapy: Consent Form | |
|------------------------------------------------------------|---------------------------------------------------------------|
| Ipilimumab for melanoma | |
| Patient identification | <input type="checkbox"/> Male <input type="checkbox"/> Female |
| | Special requirements |
| | Consultant |

Introduction

You need to give your permission before you receive any type of medical treatment or examination. Certain treatments require the permission to be recorded in writing because there are particular risks and considerations. This document is to record that an explanation has been given by an appropriate clinician and that you agree to the treatment, having assessed for yourself the processes, intended benefits and potential risks involved.

Statement of Health Professional

I have discussed the following aspects of the treatment.

The processes involved

- Ipilimumab is given as an intravenous infusion over 90 minutes every three weeks for up to four attendances.
- I have discussed the system of clinic appointments and blood tests, and how we will assess whether the drug is working.

The intended benefits

- Ipilimumab is an antibody which is designed to modify the immune system to recognise and diminish your cancer, like an immune response against an infection. There is no direct anti-cancer effect from each drug administration. Each treatment can be seen as a lesson for the immune system. Your immune health is an important contributor to the success of the treatment and I have spoken to you about how to try to optimise this.
- In around 10% of people who receive ipilimumab, the melanoma will regress. In an extra group of people, perhaps up to 30%, parts or all of the melanoma will stop growing. Unlike most other therapies which shrink cancer directly, the successful activation of your own immune response against melanoma can mean that the benefits are sustained in the longer term.
- These figures are from large clinical trials of many patients, and your individual experience may be very different. For example, ipilimumab may have no beneficial effects for you at all (and may only cause side effects: see below), or in rare instances it may be completely and permanently effective.

Side effects

- Fatigue
- Nausea and vomiting, loss of appetite
- An allergic reaction to the infusion.

- Activation of the immune system can lead to attack on your normal organs as well as, or instead of, the cancer. These are called autoimmune effects. These are usually manageable with treatments such as steroids, which reduce immune activation, but the autoimmune effects caused by ipilimumab can sometimes be prolonged, severe, have permanent consequences, or be life-threatening. These autoimmune effects can occur during treatment or months after the last dose. The systems that can be affected include the following.
 - The bowel, causing an inflammation called colitis. This can result in severe diarrhoea, prolonged hospitalisation and, rarely but importantly, surgery to remove the bowel (colectomy).
 - The lung, causing an inflammation called pneumonitis, resulting in respiratory problems.
 - The liver, causing an inflammation called hepatitis.
 - The nervous system, resulting in changes in sensation or strength, rarely progressing to paralysis and/or breathing problems.
 - The eyes, resulting in inflammation, blurred vision and other changes in eyesight.
 - Hormonal glands, resulting in temporary excess production, or more usually a loss of one or more hormones, which is liable to be permanent and require lifelong hormone replacement, for example with thyroid hormone.
 - The skin, resulting in a rash which can be widespread, severe and life-threatening.
- There are multiple other known and unknown side effects from ipilimumab (for example effects on the kidneys, pancreas, heart, the circulatory system, blood) and it is important that you carefully consider the risks of this drug.
- It is very important that you contact the hospital should you develop any unusual symptoms during or after ipilimumab, so that you can receive urgent treatment for any autoimmune effect that may be developing.

Precautions

- If you have any history of an autoimmune disorder, it is possible that ipilimumab will reactivate this. You will need to weigh up the risks and benefits of ipilimumab particularly carefully.
- If you are on chronic immunosuppressive therapy then ipilimumab may interfere with this. For example, if you have had an organ transplant, then ipilimumab treatment may lead to rejection of the organ.
- If you are taking anticoagulants (drugs that thin the blood), any bowel inflammation that results from ipilimumab may have increased risks.
- Women of childbearing potential should use effective methods of contraception during therapy and for four weeks after stopping. Men should use barrier contraception. Breastfeeding may expose a baby to adverse effects. The effects on male and female fertility are unknown.

Other considerations

- I have discussed the alternatives to this treatment and the associated risks
- I have discussed with you any special risks that might apply to you as an individual
- Additional information is attached to this form. You have agreed to read this and we will give you an opportunity to answer any further questions or concerns before you start treatment.

| | |
|----------------------------|-------|
| Clinician Signature | |
| Sign | |
| Print name | |
| Date | |
| Job title | |

Statement of Patient

- I have carefully read this form, which describes the benefits and risks of the proposed treatment.
- I have the right to change my mind at any time, including after I have signed this form
- I agree to undergo drug therapy. I understand the treatment and am aware of the potential side effects arising from the treatment.
- I understand that you cannot give me a guarantee that a particular person will perform or manage the treatment. The person will, however, have appropriate training and experience.

Patient Signature

Sign

Print name

Date

Job title

Statement of witness if required

- The patient is unable to sign but has indicated his or her consent.

Witness Signature

Sign

Print name

Date

Job title

Statement of interpreter if required

- 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.

Interpreter Signature

Sign

Print name

Date

Job title

Confirmation of consent

- Completed by the chemotherapy nurse at first treatment attendance
- 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.

| | |
|------------------------------------------|-------|
| Healthcare Practitioner Signature | |
| Sign | |
| Print name | |
| Date | |
| Job title | |

Record

- Hardcopy accepted by patient
- Hardcopy for notes
- Scanned

| | |
|------------------------|-----------------------------------------------|
| Reason for Update: N/A | Checked and approved by Consultant: Dr M Ajaz |
| Version: 1 | Date: 7.12.15 |