[TO BE PRINTED ON HOSPITAL HEADED PAPER]

GP LETTER

Date:

Dear Dr _____,

RE: Patient's Name: _____ **DOB:** ____/____/___

Address: _____

_____

ANIMATE

A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy

This patient has consented to participate in the above clinical trial which aims to assess the efficacy of nivolumab as a second or third line salvage therapy in relapsed/refractory classical Hodgkin lymphoma patients, particularly as a bridge to stem cell transplant.

The trial is being funded by Bristol-Myers Squibb Pharmaceuticals Ltd. It is sponsored by University College London and is being run by the Cancer Research UK & UCL Cancer Trials Centre.

The trial treatment patients will receive is as follows:

A PET-CT scan will be performed under trial conditions following 2 cycles of first line or second salvage (4 cycles if being treated with brentuximab vedotin) to determine eligibility for trial treatment.

- Patients who are PET-negative (Deauville 1-3) will not be eligible for trial treatment. They will enter follow up for the purpose of the trial, and any further treatment will be at their treating clinician's discretion.
- Patients who are PET-positive (Deauville 4-5) after first line salvage chemotherapy will receive 4 x 14-day cycles of nivolumab.

A further PET-CT scan will then be performed:

- Patients who are PET negative (Deauville 1-3) will stop trial treatment and enter follow up.
  Patients who are PET positive (Deauville 4-5) will have a further 4 x 14-day cycles of nivolumab, unless there is evidence of progressive disease.

Your patient is **PET-negative and will receive no further trial treatment / PET-positive and will now receive 4 x 14-day cycles of nivolumab** (delete as applicable).

Common side effects of nivolumab
A copy of the Patient Information Sheet is enclosed, however for ease of reference the main side effects are listed below:

1. Immune system related adverse effects seen in > 10% patients treated with nivolumab:

- Itching
- Rash
- Diarrhoea

2. Immune system related adverse effects seen in 5-10% patients treated with nivolumab:

- Hypothyroidism (reduction in activity of the thyroid gland). Symptoms include tiredness and weight gain
- Abnormalities of liver tests. Very rarely patients can develop a yellow colour in the eyes or abdominal pain

3. Immune system related adverse effects seen in 1-5% of patients treated with nivolumab:

- Hyperthyroidism (increase in activity of the thyroid gland). Symptoms include excessive tiredness, weight loss and palpitations.
- Pneumonitis (inflammation of the lungs). Symptoms include shortness of breath and cough
- Colitis (inflammation of the colon). Symptoms include diarrhoea and stomach pain.

Other reported side effects seen in 10% or more of patients given the drug are listed here:

- Fatigue (tiredness)
- Nausea (sickness)
- Decreased appetite
- Weakness or lack of energy

Between 1-10% of patients treated with nivolumab experience an allergic reaction to the infusion. In rare cases (less than 1% of patients) these can be severe (anaphylactic reaction).

Contraindicated medications
There are no medications/substances listed as contraindications for use with nivolumab and so there are no restrictions on what can be prescribed while the patient is on the trial.
Please note that during nivolumab treatment, patients cannot receive steroids in excess of a dose of 10mg/day prednisolone (or the equivalent dose of other steroids). If you have cause to prescribe the patient steroids during their trial treatment, please first consult their study doctor.

Pregnancy and contraception
For pregnancy and contraceptive advice, please see the attached patient information sheet.

We are collecting details of pregnancies in female trial patients and partners of male trial patients that occur during the pregnancy risk window stated by the manufacturer of nivolumab. If you are informed of a pregnancy occurring in female patient during treatment or within 6 months of completing trial treatment, or in the partner of a male trial patient during their trial treatment or within 8 months of completing trial treatment, please notify the patient's trial doctor or research nurse immediately.

Data protection
Your patient will be followed up for a minimum of 3 years after completion of treatment including if they experience disease progression/relapse, and you will be kept informed of their

progress. Should your patient fail to attend hospital clinic appointments you may be contacted for information on their current health status.

Should you have any questions concerning the patient's participation or their treatment, please contact myself or one of the **Research Nurses** on:

Consultant:

Name .....

Tel ..... or bleep **.....**

Research Nurse:

Name .....

Tel ..... or bleep **.....**

Please ensure that a copy of this letter is kept in the patient's file at your practice and that the patient is flagged as taking part in a clinical trial.

Yours sincerely,

[Signed by Investigator at site]

[insert Investigators name and position]

Enc. Patient Information Sheet