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

PATIENT REGISTRATION COVERSHEET

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:
Return fax number:
Pharmacy contact:
Pharmacy contact email address:
Pharmacy contact fax number:

Please fax to **020 7679 9861** or email between
9.00am and 5.00pm

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

Please note: forms received after 4.00pm may not be processed
until the following working day

    - All required tests/scans must be completed as per the protocol
    - The **Registration** form should be completed
- Once the above are completed you should **fax** the CTC on **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**—if sent by email, the date of birth and NHS number on page 3 must be redacted and relayed to the CTC via telephone on **0207 679 9860**. The unredacted copy should be sent to UCL CTC by post following registration.
- A member of the CTC trials team will check the eligibility criteria and **Register** the patient if all criteria are met.

Completing Forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- CRFs may only be completed by an individual delegated as responsible by the PI
- CRF Footer section
    - The "completed by" Name should be legible and CRFs should only be completed by individuals on the site delegation log
    - Each CRF should be signed and dated by the person completing the form
    - Do not complete the *For Office Use only* section
- Serious Adverse Events (SAEs) must be faxed within 24 hours of the site being aware of the event to **020 7679 9861**
- If you have any queries or require clarification about completing a CRF please contact a member of the Trial Team on **020 7679 9860**
- Completed CRFs should be sent to the CTC as per section 11.3 of the trial protocol to the address below:

ANIMATE
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

Corrections to entries

- If an error is made draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.

- **Do NOT**
    - Obscure the original entry by scribbling it out
    - Try to correct/modify the original entry

Registration Form (1/11)

Eligibility Checklist

Answers to the following statements must be Yes

	Inclusion Criteria	Yes	No	N/A
1	Age 16 or over			
2	Primary refractory classical Hodgkin lymphoma or classical Hodgkin lymphoma in first relapse			
3	About to receive or receiving first or second line salvage therapy (up to a maximum of 14 days after last treatment)			
4	Fit for autologous stem cell transplantation			
5	Written informed consent			
6	Willing to comply with the contraceptive requirements of the trial (see section 6.3.4 of the trial protocol)			

Pregnancy Test

		Yes	No	N/A
7	Negative pregnancy test in females of child bearing potential			

If Yes enter date (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Pregnancy test must be within 3 days prior to date of registration

If N/A please state reason:

Post menopausal for 12 consecutive months ☐

Total abdominal hysterectomy and/ or bilateral oophorectomy ☐

Male ☐

Other ☐
Specify below

☐

Registration Form (2/11)

Eligibility Checklist

Answers to the following statements must be no

	Exclusion Criteria	Yes	No	N/A
1	Nodular lymphocyte predominant Hodgkin lymphoma			
2	Women who are pregnant or breastfeeding			
3	History of colitis, inflammatory bowel disease or pneumonitis			
4	Patients with autoimmune disorders, except patients with vitiligo, diabetes mellitus type 1, hypo- and hyperthyroidism not requiring immunosuppressive therapy			
5	Known active hepatitis B or C infection			
6	Known HIV infection			
7	History of allergy (including severe/life threatening skin reaction) to monoclonal antibodies, anaphylaxis or uncontrolled allergy			
8	Major surgery within 4 weeks prior to registration			
9	Myocardial infarction, unstable angina, coronary artery bypass graft, cerebrovascular accident or transient ischaemic attack within the past 6 months			
10	Non-haematological malignancy within the past 3 years with the exception of (a) adequately treated basal cell carcinoma, squamous cell skin cancer, or thyroid cancer; (b) carcinoma in situ of the cervix or breast; (c) prostate cancer of Gleason grade 6 or less with stable prostate-specific antigen levels; or (d) cancer considered cured by surgical resection or unlikely to impact survival during the duration of the study, such as localised transitional cell carcinoma of the bladder or benign tumours of the adrenal gland or pancreas			

Name of person that has reviewed eligibility:
(this person must be allocated this role on the trial delegation log and document eligibility in patient medical notes)

Registration

This form should be completed only if all criteria on the Eligibility Checklist have been satisfied

Patient Information

Patient Initials ☐☐☐

Site Name ☐

Investigator ☐

Patient Date of Birth* (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

*DoB & NHS number must not be sent via email. CTC staff will phone to obtain the information.
Complete fields once registration has been confirmed via email

Sex ☐ Male ☐ Female

NHS/CHI Number* ☐☐☐☐☐☐☐☐☐☐

Details of initial diagnosis

Date of initial diagnosis (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Stage at initial diagnosis ☐ 1 = I 2 = II 3 = III 4 = IV

Subtype of Hodgkin lymphoma:

☐ Nodular sclerosing
☐ Mixed cellularity
☐ Lymphocyte rich
☐ Lymphocyte depleted
☐ Other, Specify: ☐

B symptoms present at diagnosis? ☐ Yes ☐ No
If yes, please tick all that apply below:

Registration Form (4/11)

Initial treatment for Hodgkin lymphoma

Initial treatment (please tick one option only)

ABVD	☐	BEACOPP based	☐
ABVD followed by BEACOPP based	☐	ABVD followed by AVD	☐
A2VD (AVD + Brentuximab Vedotin)	☐	Other *(Please specify)*	☐

☐

Did the patient receive radiotherapy?	☐	Yes	☐	No		
If yes, was relapse within the irradiated field?	☐	Yes	☐	No	☐	N/A

Scans during initial treatment for Hodgkin lymphoma

Interim PET-CT scan during first line treatment

Was an interim PET-CT scan performed?
If yes, please specify details below:

☐ Yes ☐ No

Date of interim PET-CT scan (DD/MM/YYYY)

☐☐☐☐☐☐☐☐

What was the result of the interim PET-CT scan?

☐ Negative
Deauville score 1-3

☐ Positive
Deauville score 4-5

End of first line treatment scan

What type of end of treatment scan was performed?

☐ PET-CT ☐ CT

☐ Not done ☐ Other
Please specify:

☐

Date of end of treatment scan (DD/MM/YYYY)

☐☐☐☐☐☐☐☐

PET-CT

☐ Complete Metabolic Response (CMR) ☐ Partial Metabolic Response (PMR)

☐ No Metabolic Response (NMR) ☐ Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT

☐ Complete Response (CR) ☐ Partial Response (PR)

☐ Stable Disease (SD) ☐ Progressive Disease

Relapse after initial treatment for Hodgkin lymphoma

Details of relapse

Date of relapse diagnosis (DD/MM/YYYY) ☐☐☐☐☐☐☐☐ ☐ N/A - Primary refractory

Stage at relapse ☐ 1 = I 2 = II 3 = III 4 = IV

B symptoms present at relapse? ☐ Yes ☐ No
If yes, please tick all that apply below:

Drenching night sweats ☐

Fever >38° C ☐

Weight Loss >10% over 6 months ☐

Was the patient anaemic at relapse? ☐ Yes ☐ No
Hb less than lower limit of normal

Number of extranodal sites at relapse? ☐☐

Treatment for relapsed/refractory Hodgkin lymphoma

Treatment at relapse (please tick one option only)

How many lines of salvage has the patient received? ☐

1 = currently or about to receive first line salvage
Complete page 7 then go on to page 9
2 = currently or about to receive second line salvage
Complete pages 7 and 8

First line salvage

Type of treatment *(Tick as applicable)*

- ESHAP ☐
- Brentuximab Vedotin ☐
- ICE ☐
- DHAP ☐
- Bendamustine ☐
- IGEV ☐
- IVE ☐
- GDP ☐
- Other *(Please specify)* ☐ ☐

Number of cycles received so far ☐

Date of response assessment if done (DD/MM/YYYY) ☐☐☐☐☐☐☐☐ OR Not due yet ☐

Date of first dose of 1st line salvage treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Response to first line salvage

PET-CT
Please see appendix 3 of the trial protocol for guidance

- ☐ Complete Metabolic Response (CMR)
- ☐ Partial Metabolic Response (PMR)
- ☐ No Metabolic Response (NMR)
- ☐ Progressive Metabolic Disease (PMD)

CT

- ☐ Complete Response (CR)
- ☐ Partial Response (PR)

Treatment for relapsed/refractory Hodgkin lymphoma: second line salvage

Complete this page only if patient is receiving or about to receive second line salvage

Type of treatment *(Tick as applicable)*

ESHAP	☐	IVE	☐
Brentuximab Vedotin	☐	GDP	☐
ICE	☐	Mini-BEAM/LEAM	☐
DHAP	☐	Gem-P	☐
IGEV	☐	Other *(Please specify)*	☐
Bendamustine	☐	☐	

Number of cycles received so far ☐

Date of first dose of 2nd line salvage treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Medical history (excluding Hodgkin lymphoma)

Enter details of all significant medical conditions, past or present, e.g. malignancies, autoimmune disorders, colitis, inflammatory bowel disease hepatitis, pneumonitis, cardiac conditions, HIV, allergies (including drug allergies). Please check eligibility list in trial protocol.
Where a condition is continuing and symptomatic (e.g. uncontrolled hypertension), please insert the CTCAE v5.0 grade.
If condition is ongoing enter C (Continuing) as End Date

Any significant medical history? ☐ Yes ☐ No *If Yes specify below:*

	Condition Please record all significant conditions Use the CTCAE v5.0 adverse event name where applicable	**Status** Resolved/ Asymptomatic = 0 Continuing = 1	**Onset Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Informed consent

Date patient information sheet given (DD/MM/YYYY) | | | | | | | | |

Date consent form signed (DD/MM/YYYY) | | | | | | | | |

Version number of the patient information sheet given to patient | | • | |

Version number of the consent form signed | | • | |

Has patient initialled all mandatory boxes? ☐ Yes ☐ No

Has patient signed and personally dated the ICF? ☐ Yes ☐ No

Name of person taking consent:
(must be on delegation log and the consent process documented in patient medical notes)

Has person taking consent signed and dated the ICF? (must be on same day as patient) ☐ Yes ☐ No

Has the patient agreed for a repeat tumour biopsy to be taken if they have a positive PET-CT scan after 8 cycles of nivolumab treatment? ☐ Yes ☐ No

Has the patient agreed to donate surplus biopsy material for use in future research? ☐ Yes ☐ No

Has the patient agreed to donate left-over blood samples for use in future research? ☐ Yes ☐ No

For women of child bearing potential:

Has the patient agreed for UCL CTC and other parties to have access to pregnancy information should they become pregnant? ☐ Yes ☐ No ☐ N/A

Registration Form (11/11)

For CTC Office Use Only

Consented by staff member on delegation log ☐

Eligibility confirmed by trial Investigator on delegation log ☐

Eligibility confirmed by CTC staff member ☐

Trial Information

Trial Number **A N M** – ☐☐☐

Date of Registration (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Registered by: _____ Signature: _____