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

POST-SALVAGE TREATMENT FAX

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 fax to **ctc.animate@ucl.ac.uk**
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

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (1/13)

PET- CT Scan

(post 2 cycles of first or second line salvage therapy or third or fourth cycle of brentuximab vedotin)

Section A

Date of scan (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Contrast-enhanced CT Scan

(if feasible, to be performed at same imaging session as PET-CT scan)

Date of scan (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

What was the result of the PET-CT central review? ☐ Negative Deauville score 1-3 ☐ Positive Deauville score 4-5

If the end of salvage PET-CT scan (PET0)was positive (Deauville 4-5), please complete sections A and B.
If the result was negative (Deauville 1-3) then please complete section A only.

Archival tumour biopsy

Has the patient's biopsy been sent for central review? ☐ Yes ☐ No Specify reason below:

☐

Specify biopsy timepoint ☐ Diagnosis ☐ Relapse

Date of Biopsy (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Date sent to HMDS (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Hospital Block/ Sample Number ☐☐☐☐☐☐☐☐☐☐

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (2/13)

Salvage Therapy

Section A

How many lines of salvage did the patient receive? ☐ One ☐ Two

First line salvage

Type of treatment *(Tick as applicable)*

☐ If full details of first line salvage (including response) already reported on Registration Form, tick this box and move to the next page.

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

☐

Number of cycles received ☐

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

Date of response assessment (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 (PD)

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ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (3/13)

Salvage Therapy

Section A

Second line salvage

Type of treatment *(Tick as applicable)* OR N/A ☐

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

Number of cycles given ☐

☐

Date of last dose of second line salvage treatment ☐☐☐☐☐☐☐☐

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ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (4/13)

Did the patient receive Radiotherapy as part of salvage? ☐ Yes ☐ No

If yes:

Date radiotherapy started (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Date radiotherapy finished (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

ANIMATE

Trial Number A N M _ ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (5/13)

Eligibility Checklist

Section B

Answers to the following statements must be Yes

	Inclusion Criteria	Yes	No	N/A
1	Has completed 2 cycles of first or second line salvage chemotherapy, (3 or 4 cycles if receiving treatment with brentuximab vedotin)			
2	PET positive (Deauville score 4 or 5) after 2 cycles of first or second line salvage chemotherapy (3 or 4 cycles if receiving treatment with brentuximab vedotin)			
3	Fit for further salvage chemotherapy			
4	ECOG performance status 0-1			
5	Creatinine clearance >30ml/min calculated by Cockcroft-Gault formula			
6	Bilirubin <1.5 x ULN, ALT/AST <2.5 x ULN			
7	Adequate bone marrow function (Hb >80g/l. Platelets >50 x 10^9/l, neutrophils >1.0 x10^9/l			

Pregnancy Test

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

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

If N/A please state reason:

Post menopausal for 12 consecutive months ☐

Total abdominal hysterectomy and/ or bilateral oophorectomy ☐

Male ☐

Other Specify below ☐

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ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (6/13)

Eligibility Checklist

Answers to the following statements must be no ***Section B***

	Exclusion Criteria	Yes	No
1	Deauville score 1-3 after 2 cycles of first or second line salvage chemotherapy (3 or 4 cycles if receiving treatment with brentuximab vedotin)		
2	Positive serology for hepatitis B or C (unless (a) hepatitis B positive due to vaccination (HBsAb positive, all other tests negative) or (b) past hepatitis B infection with low risk of reactivation (HBcAb positive & HBcAb positive, other tests negative—PI approval needed)		
3	Active infection requiring systematic therapy		
4	Ongoing requirement for immunosuppressive therapy, apart from inhaled, intranasal, topical corticosteroids or systemic corticosteroids at low doses (≤10mg prednisolone per day, or the equivalent)		
5	Chemo- or radiotherapy or corticosteroids at a dose of more than 10mg per day prednisolone or equivalent within 14 days prior to response PET-CT. NOTE: corticosteroids can be used AFTER a positive PET-CT scan for symptomatic disease but must be weaned to a dose of prednisolone ≤10mg/day or less (or equivalent) at least 7 days prior to starting nivolumab		
6	Treatment with any investigational agent within 28 days prior to planned start of nivolumab		
7	Ongoing grade 2-4 non-haematological toxicities related to prior Hodgkin lymphoma treatments, with the exception of alopecia and grade 2 fatigue		
8	Pregnant or breastfeeding women		

Name of person that has reviewed eligibility (this person must be allocated this role on the trial delegation log)

Hepatitis Serology

Date of Test (DD/MM/YYYY):	Positive	Negative	Not Done
Hep B surface antigen (HBsAg)			
Hep B surface antibody (HBsAb)	**		*
Hep B core antibody (HBcAb)	**		
Hep B antibodies or Hep B DNA (HBV DNA)			
Hep C antibodies or Hep C DNA (HCV DNA)			

* HBsAb testing only required if standard of care locally

**Serology results reviewed, and suitability for treatment confirmed, by treating clinician (name):

DD/MM/YYYY

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Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (7/13)

Post-salvage assessment

Section B

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Weight (kg) | | | | • | |

ECOG Performance Status | |

Haematology

Date of Haematology (DD/MM/YYYY) | | | | | | | | |

Haemoglobin g/L | | | | • | |

Platelets x 10^9/L | | | | |

Absolute Neutrophil Count (ANC) x10^9/L | | • | |

Absolute Lymphocyte Count (ALC) x10^9/L | | • | |

White Blood Cell (WBC) Count x10^9/L | | • | |

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ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (8/13)

Biochemistry

Section B

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

U&Es	Test Result		Test Result
Sodium mmol/L	☐☐☐☐	Magnesium mmol/L	☐☐•☐☐
Potassium mmol/L	☐☐•☐☐	Calcium mmol/L	☐☐•☐☐
Urea mmol/L	☐☐•☐☐	Urate mmol/L	☐☐•☐☐
Creatinine µmol/L	☐☐☐•☐		
Creatinine Clearance ml/min (Cockcroft-Gault)	☐☐☐•☐		

Liver Function Tests	Test Result	Upper Limit of Normal (ULN)
Albumin g/L	☐☐☐	
Bilirubin µmol/L	☐☐☐	☐☐☐
Alk. Phosphatase IU/L	☐☐☐☐	
Aspartate Transaminase (AST) IU/L	☐☐☐☐	☐☐☐☐
OR		
Alanine Transaminase (ALT) IU/L	☐☐☐☐	☐☐☐☐
Lactate dehydrogenase (LDH) IU/L	☐☐☐☐	
Glucose mmol/L	☐☐•☐☐	

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ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (9/13)

Section B

Autoimmune tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Amylase U/L | | | | **OR** Lipase U/L | | | |

ACTH ng/L | | | |

Thyroid function tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

TSH mIU/L | | | . | | |

Free T4 pmol/L | | | . | | |

Free T3 pmol/L | | | . | | | To be taken if TSH / T4 abnormal otherwise please tick this box for N/A

Lung function tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Spirometry

FEV1/FVC% | | | | FEV1% of normal | | | |

Diffusion Capacity (DLCO/TLCO)

DLCO ml/min/mmHg | | . | | Tick if not done

or

% of normal | | |

TLCO mmol/kPA/min | | . | | Tick if not done

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ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Post-Salvage Treatment Form (10/13)

Section B

ECG

Date of ECG (DD/MM/YYYY) | | | | | | | | |

Result | |

1 = Normal
2 = Abnormal - please provide details & results of echocardiogram below
3 = Abnormal, not clinically significant

Specify Abnormality

QTc interval (ms) | | |

Echocardiogram (if required)

Date of Echocardiogram (DD/MM/YYYY) | | | | | | | | |

| | N/A

Result | |

1 = Normal
2 = Abnormal - please provide details below
3 = Abnormal, not clinically significant

Specify Abnormality

LVEF | |

1 = ≤ 50%
2 = > 50%

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Post-Salvage Treatment Form (11/13)

Baseline AEs

Section B

Enter details of all significant conditions that are continuing or have developed post-registration.
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 new medical history or baseline symptoms? ☐ Yes ☐ No *If Yes specify below:*

	Condition please record all significant conditions Use the CTCAE adverse event name where Applicable, please see CTCAE v5.0 for guidance	**Status** Resolved/ Asymptomatic = 0 Continuing = 1	**Onset Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)	**Specify grade of Adverse Event**	**Treatment Ongoing** No = 0 Yes = 1*
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

* If yes, please provide details on page 11.

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Post-Salvage Treatment Form (12/13)

Additional Treatment

Section B

Has the patient taken any additional medication within 30 days prior to this visit? ☐ Yes ☐ No *If Yes specify below:*

	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Generic Drug Name	Treatment Ongoing Yes = 1 No = 0	Indication Use the CTCAE v5.0 adverse event name where applicable
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

Completed by:

Signature:

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Date completed: D D M M Y Y Y Y

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (13/13)

For CTC Office Use Only

Date Eligibility for Treatment Confirmed | | | | | | | | |

Eligibility for treatment confirmed by:

Signature:

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____