CANCER RESEARCH UK

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

UCL

EudraCT number: 2017-002544-32	Bristol-Myers Squibb Trial Reference CA-209-445

FOR UCL CTC USE ONLY	SAE ID : ANM– ☐☐☐ — ☐☐ *(file SAE Report with SAE Sponsor Review Form)*

SERIOUS ADVERSE EVENT (SAE) REPORT

Please fax this form within 24 hours of becoming aware of the SAE to the ANIMATE Coordinator at the CR UK & UCL Cancer Trials Centre on +44 (0)20 7679 9861

Section 1 - Patient details

Patient Trial Number: ANM–☐☐☐ **Patient initials:** ☐☐☐ **Age at onset:** ☐☐☐ Years **Sex:** ☐ Male ☐ Female

Height: ☐☐☐ cm **Weight:** ☐☐☐.☐ kg **Site name:** _____ **Country: UK**

This is a Report of: (Tick one box) SAE: ☐ Adverse Event of Special Interest (AESI): ☐

Section 2 - Initial report	**Date site became aware of event (s) (DD/MM/YYYY)**	**Date reported to CTC (DD/MM/YYYY)**	**If reported to the CTC after 24 hours of becoming serious, please state reason in the box below (if applicable):**

Section 3 - Follow up report (tick box if applicable) ☐

- *Initial & date all changes throughout the report.*
- *Fax to the trials centre within 24 hours of becoming aware of significant new information.*

Section 4 - Serious Events (list serious events including AESIs below) – see page 2 of template for codes

Continued on a separate sheet? ☐ Y

Event No.	**Event Term** (refer to CTCAE v5.0)	**Severity Grade** (CTCAE v5.0)	**Dates of event onset & resolution** (dd/mm/yyyy)	**Seriousness criteria[1]:** *(enter all codes applicable for each event)*	**Outcome of event[2]**	**Investigator's assessment of causal relation to event[3]:** **Nivolumab**
01			*Onset* ☐☐☐☐☐☐☐☐ *Resolution* ☐☐☐☐☐☐☐☐			
02			*Onset* ☐☐☐☐☐☐☐☐ *Resolution* ☐☐☐☐☐☐☐☐			
03			*Onset* ☐☐☐☐☐☐☐☐ *Resolution* ☐☐☐☐☐☐☐☐			
04			*Onset* ☐☐☐☐☐☐☐☐ *Resolution* ☐☐☐☐☐☐☐☐			

Codes: (1) Seriousness (enter all codes applicable to event): **1 = Required new or prolonged hospitalisation 2 = Resulted in persistent or significant disability/incapacity 3 = Resulted in congenital anomaly or birth defect 4 = Life threatening 5 = Resulted in Death 6 = Other medically significant - specify below 7 = N/A (Adverse Event of Special Interest (AESI)** *(refer to protocol)*

(2) Outcome of Event (enter one code per event)**: 1 = Not Resolved 2 = Resolved 3 = Resolved with Sequelae 4 = Resolving 5 = Fatal**

(3) Causal Relationship (enter one code)**: 0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

If patient has died:	**Date of death:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	**Cause of death:** *(specify)* _____	**Autopsy report available?** *(this may be requested by UCL CTC if required)* Y ☐ N ☐
Dates of hospitalisation when seriousness criterion 1 is chosen:	**Date of hospitalisation:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	**Date of discharge:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	
If an event(s) is medically significant, specify why:			

Section 5 - IMPs — **Most recent cycle number:** ☐

Active Substance	Brand Name	Batch Number	Formulation	Route	Protocol Dose	Frequency	Total Daily Dose Prior to Event Onset	Treatment error[1]	Date of First Administration of IMP AND Date of Final Administration of IMP (or tick "Ongoing" if treatment continued to date) AND Date of last IMP administration prior to event onset (dd/mm/yyyy)	Action Taken[2]	*Complete if dose reduced/treatment stopped* Y or N or N/A or UNK: Event(s) improved after stopping or reducing treatment?	Was the drug re-introduced?	If yes, did the event(s) reappear once reintroduced?
Nivolumab	Opdivo®		Solution for infusion	IV	240mg				*First* ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing* *Date of last administration prior to SAE* ☐☐ ☐☐ ☐☐☐☐				

Codes:

(1) Enter one code: 0 = No issues 2 = Overdose 3 = Medication error 4 = Other: specify_____

(2) Action taken: 1 = Drug withdrawn permanently 2 = Drug withdrawn temporarily 3 = Dose not changed 4 = Unknown 5 = Not applicable (e.g. treatment not started/completed prior to SAE onset)

Section 6 - Any relevant tests/laboratory data applicable to this SAE? Y ☐ N ☐ If yes, specify below *Continued on separate page?* ☐ Y

Date *(dd/mm/yyyy)*	**Test** *(specify)*	**Results** *(specify and include units, if applicable)*	**Results Pending** *(tick box if result has not been provided)*	**Normal range, if applicable** *(specify and include units, if applicable)*
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Section 7 – Any other non-serious events relevant to this case? Y ☐ N ☐ *If yes, list adverse event term below, with start and stop dates*

Section 8 - Any relevant medical history/concurrent conditions (both patient and family)? Y ☐ N ☐ *If yes, specify below with start and stop dates*

Section 9 - Treatment for SAE? Y ☐ N ☐ If yes, specify below. Please provide all relevant details available (indication, dose, frequency, start and stop dates)

Section 10 - Concomitant medications? Y ☐ N ☐   If yes, specify below   *Only include drugs given within the 30 days prior to SAE onset excluding treatment for SAE. Use continuation page if necessary.*   *Continued on separate page?* ☐ Y

Drug Name	Indication	Dose (include units)	Frequency	Route	Start date AND Stop Date or Ongoing (dd/mm/yyyy)
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*

Section 11 - Were any SAEs listed on this form related to a concomitant medication? Y ☐ N ☐   *If yes, give details of adverse event term, drug name and if there was an interaction with the IMP*

Event Term (state Event Term as given in Serious Events section)	**Concomitant Medication** (list which concomitant medication is related to adverse event)	**Was the AE as a result of an interaction between the IMP and concomitant medication?**
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐

Section 12 - Case Narrative

Continued on a separate sheet? ☐ Y

Section 13 - Investigator Assessment: *(must be authorised on staff delegation log to review SAEs and perform evaluations of causal relationship)*

Print Name: _____ **Signature:** _____ **Date of Assessment:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

Section 14 - Form(s) completed by: *(must be authorised on staff delegation log to complete CRFs and report SAEs)*

Print Name: _____ **Signature:** _____ **Date of Completion:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

Continuation pages

Section 4 - Serious events (continuation page)

Event No.	Event Term (refer to CTCAE v5.0)	Severity Grade (CTCAE v5.0)	Dates of event onset & resolution (dd/mm/yyyy)	Seriousness criteria[1]: *(enter all codes applicable for each event)*	Outcome of event[2]	Investigator's assessment of causal relation to event[3]: Nivolumab
05			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
06			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
07			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
08			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
09			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
10			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			

Codes:

(1) Seriousness (enter all codes applicable to event): **1 = Required new or prolonged hospitalisation 2 = Resulted in persistent or significant disability/incapacity 3 = Resulted in congenital anomaly or birth defect 4 = Life threatening 5 = Resulted in Death 6 = Other medically significant - specify below 7 = N/A (Adverse Event of Special Interest (AESI)** *(refer to protocol)*

(2) Outcome of Event (enter one code per event)**: 1 = Not Resolved 2 = Resolved 3 = Resolved with Sequelae 4 = Resolving 5 = Fatal**

(3) Causal Relationship (enter one code)**: 0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

Section 6 - Tests/laboratory data (continuation page)

Date *(dd/mm/yyyy)*	Test *(specify)*	Results *(specify)*	Results Pending *(tick box if result has not been provided)*	Normal range, if applicable *(specify)*
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Section 9 - Concomitant medications (continuation page)

Drug Name	Indication	Dose (include units)	Frequency	Route	Start date AND Stop Date or Ongoing (dd/mm/yyyy)
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
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					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing

Section 10 - Treatment for SAE (continuation page)

Treatment	Indication	Dose (include units)	Frequency	Route	Start date AND Stop Date or Ongoing (dd/mm/yyyy)
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
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					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
					Start ☐☐ ☐☐ ☐☐☐☐ Stop ☐☐ ☐☐ ☐☐☐☐ ☐ Ongoing
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Section 12 - Case Narrative (continuation page)