ANIMATE

PREGNANCY REPORT

Please complete all sections with details of any pregnancy occurring from the first administration of nivolumab until 6 months after last trial treatment administration for trial patients **or** if the female partner of a male trial patient becomes pregnant between the start of trial treatment and 8 months after last trial treatment administration

Please fax this form to the ANIMATE Coordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours of notification of the event.

Trial details					
Trial title:	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				
Trial acronym:	ANIMATE	**EudraCT number:**	2017-002544-32	**Bristol- Myers Squibb Trial Reference:**	CA-209-445

Patient details *(Any information regarding female partners of trial patients should be entered in Other Pregnancy Information section)*			
Patient initials:	☐☐☐	**Patient trial number:**	**ANM -** ☐☐☐
Age at time of conception:	☐☐ Years	**Pregnancy report relates to:**	☐ Trial Patient ☐ Partner of Trial Patient
Hospital:		**Treating Clinician:**	

Type of report:	☐ **Initial** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*	☐ **Follow-up**	**For all follow-up reports, please:** • **initial & date all changes throughout the report.** • **fax to the trials centre within 24 hours of becoming aware of significant new information.**

Complete for initial reports only:	**Date site notified of pregnancy:** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*	**If reported to the CTC more than 24 hours after becoming aware of pregnancy, provide reason:**	_____

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Patient trial number: ANM – ☐☐☐

IMP											**Most recent cycle number:** ☐
Name	**Manufacturer Name AND Brand Name**	**Batch Number**	**Strength (include units)**	**Total Daily Dose last given prior to Pregnancy confirmation** (include units)	**Frequency**	**Formulation**	**Route**	**Treatment Overdose[1]**	**Date of first administration of IMP** dd – mm – yyyy	**Date of last administration of IMP prior to pregnancy confirmation** dd – mm – yyyy	**Action Taken[2]**
Nivolumab	**Bristol-Myers Squibb - OPDIVO**		**10mg/ml**			**Concentrate for solution for infusion**	**IV**	☐	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐

Codes:
(1) Enter one code: 0 = no overdose 1 = dosing/administration error by site 3 = Other (specify) _____
(2) Action taken: 0 = Dose not changed 1 = Dose reduced 2 = Drug withdrawn/Treatment stopped
SEE PROTOCOL FOR ACTION THAT SHOULD BE TAKEN ON CONFIRMATION OF PREGNANCY (If action differs, give details in Other Pregnancy Information)

Pregnancy Information						
Start date of last menses	**Date pregnancy confirmed**	**Method of diagnosis**		**Anticipated date of childbirth**		**Mother consented for pregnancy monitoring?**
☐☐ ☐☐ ☐☐☐ d d m m m y y	☐☐ ☐☐ ☐☐☐ d d m m m y y			☐☐ ☐☐ ☐☐☐ d d m m m y y		☐ Y ☐ N ☐ Pending *
If consented for pregnancy monitoring:	☐ Trial patient, consented at study entry	If not consented at study entry (i.e. partners)	Date consent signed ☐☐ ☐☐ ☐☐☐ d d m m m y y	Pregnancy monitoring PIS version used:	☐.☐	Pregnancy monitoring consent form version used:	☐.☐
*** If mother has not yet consented for pregnancy monitoring:**	☐ Will be consented at next clinic visit	☐ Other (specify): _____					

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Pregnancy Outcome – Complete the section *only if* the mother has given consent						*Please provide any further information in Other Pregnancy Information section below*
☐ Not known at this date	☐ Live birth/ healthy baby	☐ Induced abortion[1]	☐ Spontaneous abortion[1]	☐ Still birth[1]	☐ Neonatal death[1]	Date of Pregnancy outcome: ☐☐ ☐☐ ☐☐☐☐ dd – mm - yyyy
Was there any evidence of congenital abnormalities?	☐ Yes[1]	☐ No	☐ Not known			

(1) For adverse pregnancy outcomes please provide further information in the narrative and ensure a clinician assesses causality	Adverse outcome causally related to IMP? ☐ Y* ☐ N	Adverse outcome causally related to Concomitant Medication? ☐ Y ☐ N	*SAE report submitted? ☐ Y* ☐ N	*SAE report must be submitted within 24 hours of becoming aware of adverse outcome*

* *Please complete and submit an SAE form for all adverse outcomes deemed to be causally related to trial treatment. IMP sections do not need to be duplicated on the SAE Report if provided on the Pregnancy Report.*

Date of delivery dd – mm – yyyy	**Gestation (weeks)**	**Mode of Delivery**	**Sex**	**Weight (kg)**	**Antenatal Problems**	**Postnatal Problems**
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		

If multiple birth, please provide the above details for each additional baby under 'Other Pregnancy Information' below

Other Pregnancy Information– Complete the section *only if* the mother has given consent
(e.g. action taken, concurrent conditions, medical history, complications during birth, birth defects, causality details etc.)

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Past Pregnancy History – Complete the section *only if* the mother has given consent						
Date of delivery dd – mm – yyyy	**Gestation (weeks)**	**Mode of Delivery**	**Sex**	**Weight (kg)**	**Antenatal Problems**	**Postnatal Problems**
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		

Relevant concomitant medications? ☐ N ☐ Y

Complete the section *only if* the mother has given consent

Only include drugs given before or during pregnancy considered relevant any adverse pregnancy outcome. Use continuation page if necessary.

Continued on separate page? ☐ Y

Drug Name	**Brand**	**Indication**	**Total Daily Dose Prior to Pregnancy Confirmation** (include units)	**Frequency**	**Route**	**Date of First Administration of Drug AND Date of Last Administration of Drug Prior to Pregnancy Outcome** (dd/mm/yyyy)
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐

Investigator Assessment: *(must be authorised on staff delegation log to review pregnancies and perform assessment of causal relationship)*

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

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

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

Concomitant medications (Continuation page)   Complete the section *only if* the mother has given consent
Only include drugs given before or during pregnancy considered relevant any adverse pregnancy outcome.

Drug Name	Brand	Indication	Total Daily Dose Prior to Pregnancy Confirmation (include units)	Frequency	Route	Date of First Administration of Drug AND Date of Last Administration of Drug Prior to Pregnancy Outcome (dd/mm/yyyy)
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
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						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐