EudraCT number: 2014-000506-35	Amgen Reference: IST-CAR-567 (20159848)	FOR UCL CTC USE ONLY	SAE ID: CAR — ☐☐☐ — ☐☐☐ *(file SAE Report with SAE Sponsor Review Form)*

SERIOUS ADVERSE EVENT (SAE) REPORT

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

Patient details

Patient Trial Number: CAR– ☐☐☐ **Patient initials:** ☐☐☐ **Age at onset (years):** ☐☐ **Sex:** ☐ M ☐ F **Height:** ☐☐☐ cm **Weight:** ☐☐☐.☐ kg

Site name: _____ **Country: United Kingdom**

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

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/email to the trials centre within 24 hours of becoming aware of significant new information.**

Date site notified of SAE: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

If reported to the CTC after 24 hours of becoming aware of SAE, provide reason:
- Patient admitted to another hospital ☐
- Patient admitted to another dept at site ☐
- Other reasons ☐ *specify* _____

Serious Events *(list serious events only)*

Continued on a separate sheet? ☐ Y **Total No. of Events** ☐☐

Event No.	Event Name (refer to CTCAE v4.03)	Severity Grade (CTCAE v4.03)	Dates of Onset & Resolution dd-mm-yyyy	Outcome of Event[1]	Causal relation to event[2]: *(enter one code for each treatment)*		
					Carfilzomib	Cyclophosphamide (N/A in maintenance)	Dexamethasone (N/A in maintenance)
1		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
2		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
3		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
4		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
5		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐

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

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

CARDAMON SAE Report

Patient Trial Number: CAR– ☐☐☐ **Initials** ☐☐☐

Why was the SAE serious? *(tick all that apply – please refer to the Pharmacovigilance section of the protocol for details)*

Resulted in death	☐	
Life threatening	☐	
Required new or prolonged hospitalisation	☐	**For new hospitalisations only:** *dd-mm-yyyy* Date of admission: ☐☐ ☐☐ ☐☐☐☐ Date of discharge: ☐☐ ☐☐ ☐☐☐☐
Resulted in persistent or significant disability/incapacity	☐	
Resulted in congenital anomaly or birth defect	☐	
Other medically significant *(e.g. non-serious adverse events of special interest)*	☐	*specify* _____

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)* ☐ N ☐ Y

IMPs **Most recent treatment phase:** *(please select one)*

I = Induction
*C = Consolidation **or***
A = ASCT
M = Maintenance

☐

Trial arm:
☐ Consolidation
☐ ASCT *(Complete details below)*
☐ N/A - Not yet randomised

Most recent cycle: ☐☐

NB: for patients receiving maintenance treatment, please complete details for Carfilzomib only in the table below (details of supportive dexamethasone in maintenance should be added to the 'concomitant medications' section)

Name	Manufacturer Name AND Brand Name	Batch Number	Strength *(include units)*	Total Daily Dose Prior to SAE (include units)	Frequency	Formulation *(delete as appropriate)*	Route	Treatment Overdose[1]	Date of First Administration of IMP AND Date of Last Administration of IMP Prior to this SAE AND Date of Final administration of IMP (or tick ongoing if treatment continued to date) dd-mm-yyyy	Action Taken[2]	Dechallenge/Rechallenge *(complete if dose reduced/treatment stopped)* Y or N or N/A: Event(s) improved after stopping or reducing treatment	Was a rechallenge performed?	If yes, did the event(s) reappear once reintroduced?
Carfilzomib	**Amgen**		**60mg**			**Lyophilisate for solution**	**IV**	☐	*First* ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐ *Final* ☐☐ ☐☐ ☐☐☐☐ Ongoing ☐	☐	☐	☐	☐
Cyclophosphamide					**Days 1, 8 & 15 of 28 day cycle**	**Tablet OR Powder for solution for injection or infusion**		☐	*First* ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐ *Final* ☐☐ ☐☐ ☐☐☐☐ Ongoing ☐	☐	☐	☐	☐
Dexamethasone					**Days 1, 8, 15 & 22 of 28 day cycle**	**Tablet OR Solution for injection**		☐	*First* ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐ *Final* ☐☐ ☐☐ ☐☐☐☐ Ongoing ☐	☐	☐	☐	☐

Codes:
(1) Enter one code: 0 = no overdose 1 = dosing/administration error by site 2 = accidental/intentional overdose by patient 3 = Other (specify) _____
(2) Action taken: 0 = Dose not changed 1 = Dose reduced 2 = Drug withdrawn/Treatment stopped 3 = Treatment not yet commenced

ASCT (if patient randomised to this Arm)

Start date of Melphalan conditioning: ☐☐ ☐☐ ☐☐☐☐ *(d d m m y y y y)* End date of Melphalan conditioning: ☐☐ ☐☐ ☐☐☐☐ *(d d m m y y y y)* Date of Transplant Day 0: ☐☐ ☐☐ ☐☐☐☐ *(d d m m y y y y)*

Any tests/laboratory data applicable to this SAE? ☐ N ☐ Y *If yes, specify below*	**Continued on a separate sheet?** ☐ **Y**

Date *(dd/mm/yyyy)*	**Test** *(specify)*	**Results** *(specify units and normal ranges)*	**Normal range, if applicable** ***(specify and include units, if applicable)***	**Results Pending** *(check box if result has not yet been provided)*
☐☐ ☐☐ ☐☐☐☐				☐
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Any non-serious events relevant to this case? ☐ N ☐ Y *If yes, list Adverse Event Term below, with start and stop dates*

Any relevant medical history/concurrent conditions? ☐ **N** ☐ **Y** *(If yes, Please specify details below)*

Treatment for SAE? ☐ N ☐ Y *If yes, specify below, include: drug name, indication, formulation, dose (including unit), frequency, route, start and end dates*

Continued on a separate sheet? ☐ Y

CARDAMON SAE Report

Patient Trial Number: CAR– ☐☐☐ **Initials** ☐☐☐

Concomitant medications? ☐ N ☐ Y	*If yes please complete the Concomitant Medication Sheet.*

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

Event Name (State term as provided 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?**
		☐ N ☐ Y
		☐ N ☐ Y
		☐ N ☐ Y
		☐ N ☐ Y
		☐ N ☐ Y

Case Narrative *(Give a concise medical description of the events including all relevant signs and symptoms, body systems, and any additional information deemed relevant to the case. State the rationale for causal relationship between the event and trial treatment, include medical judgement considering all relevant factors.)*

Continued on a separate sheet? ☐ Y

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

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

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*

For UCL CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____