Cancer Research UK & UCL Cancer Trials Centre **CARDAMON** **ADVERSE EVENT FORM**

Trial No: CAR - ☐☐☐ **Initials:** ☐☐☐ **Date of assessment:** ☐☐☐☐☐☐☐☐ (d d m m y y y y) **Site:** _____

IMPs **Most recent treatment phase:** *(please select one)*
I = Induction
*C = Consolidation **or***
A = ASCT
M = Maintenance
☐

Trial arm:
☐ Consolidation
☐ ASCT
☐ N/A - not yet randomised

Most recent cycle: ☐☐

Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade** [1] *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria** [2]	**SAE Report Submitted** *0 = No 1 = Yes* [3]	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome** [4]	**Causal relationship with Carfilzomib**[5]	**Causal relationship with Cyclophosphamide**[5] (N/A in Maintenance unless long term effect)	**Causal relationship with Dexamethasone**[5] (N/A in Maintenance unless long term effect)
Alopecia	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Neutrophil count decreased	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Platelet count decreased	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Anemia	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Neuropathy (motor)	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Neuropathy (sensory)	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Diarrhea	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Nausea	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Vomiting	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Fatigue	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐
Dizziness	☐	☐	☐	Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐	☐	☐	☐	☐

1) Enter worst grade observed during reporting period / Use CTCAE v4.03 where possible
2) Enter code: 0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant
3) If yes, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt and it is not related to a trial treatment, including maintenance treatment
4) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
5) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

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Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade [1]** *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria [2]**	**SAE Report Submitted** *0 = No 1 = Yes [3]*	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome [4]**	**Causal relationship with Carfilzomib[5]**	**Causal relationship with Cyclophosphamide[5]** (N/A in Maintenance unless long term effect)	**Causal relationship with Dexamethasone[5]** (N/A in Maintenance unless long term effect)
Back Pain	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Rash pustular	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Rash acneiform	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Rash maculo-papular	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Hypertension	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Dyspnea	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Acute kidney injury	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
Lung infection	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐

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

Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade** [1] *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria** [2]	**SAE Report Submitted** *0 = No 1 = Yes* [3]	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome** [4]	**Causal relationship with Carfilzomib**[5]	**Causal relationship with Cyclophosphamide**[5] (N/A in Maintenance unless long term effect)	**Causal relationship with Dexamethasone**[5] (N/A in Maintenance unless long term effect)
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐
	☐	☐	☐	Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐	☐	☐	☐	☐

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3) If yes, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt and it is not related to a trial treatment, including maintenance treatment
4) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
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FORM COMPLETED BY: **Print name:** ______________________ **Signature:** ______________________ **Date:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

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Completion Instructions

- **Record all adverse events (AEs) that occur from informed consent until 30 days post last trial treatment administration whether related to the trial treatment or not.**
- **Pre-existing events do not qualify as AEs unless they worsen.**
- **All AEs added to the form (not pre-printed) must be added to subsequent forms until they have resolved.**

1) Severity Grade

- Enter worst grade observed since last cycle
- Use CTCAE v4.03 where possible
- If no AE occurred enter "0" and do not complete the columns to the right

2) Seriousness Criteria

- Use the following options: **0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant**

3) SAE Report Submitted

- Ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt and it is not related to a trial treatment, including maintenance treatment

4) Outcome

- Use the following options: **0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown**

5) Causal relationship with

- Use the following options: **0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

Note: The expression *'reasonable suspected causal relationship'* is meant to convey in general that there is reason (e.g. facts, evidence or arguments) to suggest a causal relationship. Therefore, if you consider an AE to be either *Definitely*, *Probably* or *Possibly* related to the IMP, select *1= Related (reasonable possibility) to a trial treatment*. AEs considered to fall within the *Unlikely* or *None* categories map to *Not related (no reasonable possibility) to a trial treatment*.

Please return to: Cardamon Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

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