Cardamon

Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

1st Progression/Relapse Form

Patient Initials	☐☐☐
Trial Number	C A R – ☐☐☐

(This form has 7 pages including cover sheet)

Please send forms to:

Cardamon Trial Coordinator
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

General enquires: **020 7679 9860**
Randomisations: **020 7679 9860** between 9.00am and 5.00pm
Fax: **020 7679 9861**
E-mail: **ctc.cardamon@ucl.ac.uk**

Additional instructions for completing forms

The 1st progression/Relapse Form should be completed at the time of first relapse.

Completing forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- **Do not leave any fields blank. In case of missing data**
  - ND (not done) if a test has not been performed or a measure not taken. If applicable state the reason
  - NA (not applicable) if a measure is not applicable
  - NK (not known) if data is unknown. This should only be used once every effort to obtain the data has been exhausted.
- CRFs may only be completed by an appropriately qualified individual delegated as responsible by the PI on the site delegation log
- CRF Footer section
  - The "completed by" Name should be legible
  - Each CRF should be signed and dated by the person completing the form
  - Do not complete the *UCL CTC Use only* section
- **The CRF should be sent/faxed to the Cancer Trials Centre (CTC) with a copy retained at the Site** (ensure when photocopying the page that the copy is added to the CRF booklet in the same place where the original was stored)

If you have any questions about how to complete this form please contact the Cardamon Trial Coordinator on: 020 7679 9860

1st Progression/Relapse Form

Haematology

Date of Haematology: D D M M Y Y Y Y

Haemoglobin g/dL

WBC Count x10^9/L

Platelets x 10^9/L

Lymphocytes x 10^9/L

Neutrophils x10^9/L

Biochemistry

Date of Biochemistry D D M M Y Y Y Y

Calcium (corrected) mmol/L

Bilirubin µmol/L

Potassium mmol/L

Albumin g/L

Sodium mmol/L

Alkaline Phosphatase IU/L

Creatinine µmol/L

Alanine Transaminase (ALT) IU/L

Or

Creatinine Clearance ml/min

Aspartate Transaminase (AST) IU/L

Serum urate µmol/L

Phosphate mmol/L

Urea (mmol/L)

Bone marrow biopsies

Bone marrow aspirate Date of sample D D M M Y Y Y Y

☐ 1= Present, complete % of plasma cells: ☐☐☐ %
2= Present , not measured
3= Absent
4= Not done

Bone marrow trephine Date of sample D D M M Y Y Y Y

☐ 1= Present, complete % of plasma cells: ☐☐☐ %
2= Present , not measured
3= Absent
4= Not done

Bone marrow aspirate and peripheral blood samples must also be sent to the UCL Cancer Institute Myeloma Lab at relapse
N.B: Sites unable to perform cytogenetics/FISH must send an additional 4-8ml of BM aspirate to the UCL Cancer Institute Myeloma Lab

	Sent? 1=Yes 2= No	**Date sample sent to lab**
BM aspirate for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab	☐	D D M M Y Y Y Y
Peripheral blood sample for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab	☐	D D M M Y Y Y Y

If No to any of the above, specify a reason: ☐

Soft tissue plasmacytoma/Extramedullary lesions

Does the patient have any soft tissue plasmacytomas/ Extramedullary lesions? ☐ 1= Yes, complete date of test and a separate line for each site involved
2= No

If yes, date of test D D M M Y Y Y Y

			Long axis	**Short axis**
Site involved:	☐	Bidimensional measurements (cm):	☐	X ☐
Site involved:	☐	Bidimensional measurements (cm):	☐	X ☐
Site involved:	☐	Bidimensional measurements (cm):	☐	X ☐

1st Progression/Relapse Form

To be completed upon first disease progression/relapse.

Efficacy assessments

Date of test [D][D][M][M][Y][Y][Y][Y]

Please complete this section for all myeloma patients:

Paraprotein expression *(choose one option only)* [ ]
1= Single paraprotein expressed
2= Light chain only
3= Biclonal
4= Non-secretory

Paraprotein type key: 1 = IgG, 2 = IgA, 3 = IgM, 4 = IgD

Specify paraprotein type: [ ] Serum paraprotein [ ] 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done [ ][ ][ ] (g/L)

Specify paraprotein type: *(If biclonal)* [ ] Serum paraprotein [ ] 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done [ ][ ][ ] (g/L)

Serum free light chain: Kappa (mg/L) [ ][ ][ ] • [ ][ ] **OR** [ ] Tick if not done

Serum free light chain: Lambda (mg/L) [ ][ ][ ] • [ ][ ] **OR** [ ] Tick if not done

Serum free light chain Kappa/Lambda ratio: [ ][ ][ ] • [ ][ ] Normal range of Kappa/Lambda FLC ratio: [ ] – [ ]

Urinary light chain measurement

[ ] 1= Present, quantifiable
Please complete 24h BJP result (in g/24h): [ ][ ][ ] • [ ]
2= Too faint to quantify (24h BJP only)
3= Absent
4= Not done
5= Present, not formally quantified
(if unable to perform 24h BJP)

Light chain type *(please choose one only):* [ ] 1= Kappa 2= Lambda 3 = N/A

UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: _____

1st Progression/Relapse Form

Imaging ***(If clinically indicated or for response assessment if persistent soft tissue plasmacytomas present)***

		Date of test	Lytic or focal lesions? 1= Yes 2= No
MRI	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
CT	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
PET	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
Skeletal survey	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
Other imaging	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	

Specify type of other imaging

Has an increase in number or size of lytic bone lesions been seen on any radiograph? 1 = Yes 2 = No

1st Progression/Relapse Form

Date of **first** Progression/Relapse D D M M Y Y Y Y

Has progression been confirmed by cytogenetics/FISH? ☐ 1=Yes 2= No; *please provide reason cytogenetics/FISH not performed:*

Please specify the nature of disease progression in the table below: 1=Yes *(See Appendix 3 for further details)* 2=No

≥25% increase in serum paraprotein (absolute increase ≥5g/l)	
≥25% increase in urine light chain excretion (absolute increase ≥200mg/24h)	
≥25% increase in the difference between involved and uninvolved light chains (absolute increase ≥100mg/l)	
≥25% increase in bone marrow plasma cell percentage (absolute increase ≥10%)	
Development of new lytic bone lesions or soft tissue plasmacytomas	
Definite increase in the size of existing bone lesions or soft tissue plasmacytomas	
Development of hypercalcaemia (>2.8mmol/l) attributed solely to myeloma	
Other, please specify below: _____	

Further Treatment Plan:

Is further myeloma treatment planned? *(choose one option only)* ☐ 1= Yes *(please complete treatment details and start date below)* 2= Palliation/no further treatment 3= Watch and wait or not known at present

If **Yes**, please specify the treatment:

and provide the start date : D D M M Y Y Y Y

Is Salvage ASCT planned for this patient in second remission? ☐ 1= Yes 2= No, please complete below 3= Not known at this time, please amend this form once this information is available

If **No**, please specify a reason for not planning to proceed to salvage ASCT:

Please ensure that in the case of treatment-related disease progression, an SAE form is completed and faxed/emailed to UCL CTC within 1 business day of the site becoming aware.

Name of person completing form: Signature of person completing form: Date completed: D D M M Y Y Y Y

The site PI or delegated investigator must sign to confirm that information within the CRF is accurate

Investigator name: Investigator signature: Date completed: D D M M Y Y Y Y

UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: _____