Cardamon

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

2nd Progression/Relapse Form

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

(This form has 4 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 2nd Progression/Relapse Form should be completed at the time and in the event of a second 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 if not required
  - 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

2nd Progression/Relapse Form

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

2nd Progression/Relapse Form

To be completed upon second disease progression/relapse.

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

Please specify the nature of disease progression in the table below: 1= Yes 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: _____	

*with respect to nadir values after first progression

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/not known at present *(please provide update when known)*

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

If yes, please provide a start date : D D M M Y Y Y Y

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