(TO BE PRINTED ON HOSPITAL HEADED PAPER)

GP LETTER

Date:

Dear Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

RE: Patient’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Cardamon trial**

**Study title:** Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT (UCL 12/0500)

This patient has consented to participate in the above clinical trial. The trial is being funded by Amgen Ltd. It is sponsored by University College London and is being run by the Cancer Research UK & UCL Cancer Trials Centre.

The main aim of this study is to determine the efficacy of the novel triplet regime of carfilzomib, cyclophosphamide and dexamethasone as induction treatment in untreated patients with symptomatic multiple myeloma and to determine the benefit of upfront Autologous Stem Cell Transplant (ASCT).

All patients will be treated with 4 cycles of Carfilzomib, cyclophosphamide and dexamethasone (CarCyDex). Dependent on their response, they may then be randomised to receive either an ASCT with melphalan conditioning or 4 further cycles of CarCyDex. If patients respond well, they will then receive maintenance therapy with carfilzomib for 18 months.

High dose mephalan conditioning and ASCT are standard treatment for multiple myeloma and are being given according to local protocols.

Carfilzomib is licensed for use in multiple myeloma inpatients who have received at least one prior treatment in the UK. There is therefore limited safety data as to its use as first line treatment for multiple myeloma as part of triplet regimen.

A copy of the Patient Information Sheet is enclosed, however for ease of reference the most common side effects of carfilzomib treatment are: fatigue, anaemia, nausea, thrombocytopenia, neutropenia, shortness of breath, diarrhoea, vomiting, fever, chills increases in liver enzymes and blood creatinine, back pain and insomnia.

Less common side effects that have been reported and may be related to carfilzomib therapy are thrombotic microangiopathy, decreased or worsening heart function, kidney failure, worsening liver function, inflammation of the pancreas and tumour lysis syndrome.

Pregnancy and contraception

For pregnancy and contraceptive advice please see the attached patient information sheet. Female patients of childbearing potential on the Cardamon trial consent to use a highly effective method of contraception until 12 months post last trial treatment administration. Male patients with partners of childbearing potential consent to use condoms until 12 months post last trial treatment administration.

If you are informed of a pregnancy occurring in either a female patient, or partner of a male patient, please notify the patient’s trial doctor or research nurse immediately.

**Contraindicated medications**

There are no known contraindicated medications for Carfilzomib treatment however concurrent therapy with an approved or investigative anticancer therapeutic with activity against multiple myeloma is not allowed. Other investigative agents (e.g., antibiotics or antiemetics) should not be used during the study. Please note that vaccinations / skin tests are not appropriate while the patient is receiving trial treatment.

Data protection

Your patient will be followed up every 6 months for 10 years after completion of induction treatment and you will be kept informed of their progress. Should this patient be unable to be followed up at the hospital or fail to attend hospital clinic appointments you may be contacted for information on their current health status.

Should you have any questions concerning the patient’s participation or their treatment, please contact myself or one of the Research Nurses, on:

Tel ........................................................………… or bleep ..................................................

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Consultant

Tel ........................................................………… or bleep ..................................................

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Research Nurse

Please ensure that a copy of this letter is kept in the patient’s file at your practice and that the patient is flagged as taking part in a clinical trial.

Many thanks and best wishes

Signed by Investigator at site

Enc. Patient Information Sheet