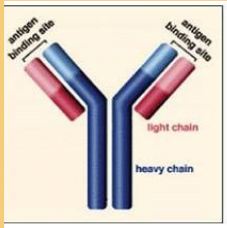
Number 2
June 2015

LEUKAEMIA & LYMPHOMA RESEARCH
Beating Blood Cancers

EudraCT No. 2012-003947-31
Ethics Ref: 13-NE-0361



OPTIMAL

Optimising Renal outcome in Myeloma renal failure

A study of Thalidomide, Bendamustine & Dexamethasone (BTD) Vs Bortezomib, Bendamustine & Dexamethasone (BBD) in patients with renal failure defined as GFR below 30 mls/min

Hello All,

A warm welcome to the second news letter. Thank you for your interest in the OPTIMAL study.

Significant progress has been made this year with OPTIMAL study. 2 patients have been recruited on the study at Oxford, which is the only site currently open. No major issues identified with the drug supplies or safety concerns with the study medications so far. Key aim is to keep the momentum through the summer and get as many sites open as possible. Thank you for your immense support.

RANDOMISATION: Warwick Clinical Trials Unit (WCTU) will be randomising the patients. Randomisation can be performed between Monday and Friday from 09:00 AM to 5:00PM

To **randomise** a patient please call **Warwick Clinical Trials Unit** on: **02476 150 402**

DRUG ORDERS: The completed drug order forms can be sent to the OPTIMAL Trial Coordinator, who will process the drug orders. BORTEZOMIB and BENDAMUSTINE are supplied free of cost by the drug companies.

Please send completed **drug order forms** to: **optimal.trial@nhs.net**

OPTIMAL TRIAL OFFICE: The OPTIMAL Trial office is open Monday-Friday 0900-1700. The Trial coordinator can be approached on 01865 223 353 or on email optimal.trial@nhs.net

FAX SAEs to OPTIMAL Trial Office: **01865 572 035**

NEWSLETTER

Oxford University Hospitals NHS
NHS Trust

LEUKAEMIA & LYMPHOMA RESEARCH
Beating Blood Cancers

OPTIMAL

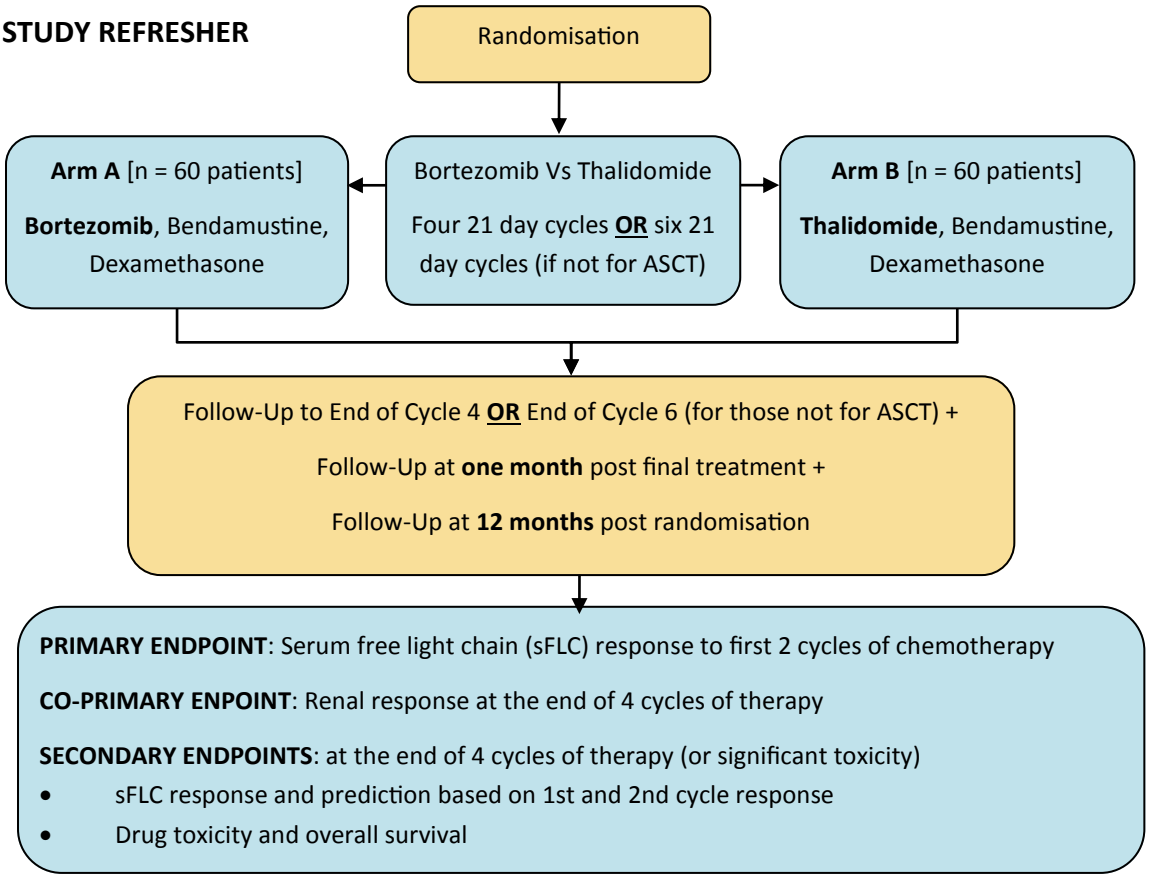
TRIAL UPDATE

- Two patients randomised at Churchill Hospital, Oxford.
- Sites actively setting up this quarter: Great Western– Swindon, Royal Liverpool– Liverpool, Queen Alexandra- Portsmouth, Epsom St Helier– Surrey, Kings College– London, and Heart of England– Birmingham
- The Trial centre is looking into the possibility of creating a eCRF and provide remote access to the research team, so updating data becomes easier. (Although the SAE form will be kept as paper for ease of completion)
- The Trial centre will be convening for a steering committee meeting to discuss the progress of the study.

Goal for the Next 3 months

- Open a minimum of 3 additional sites and randomise up to 5 patients

STUDY REFRESHER



Oxford University Hospitals NHS
NHS Trust

Dr Karthik Ramasamy;

Chief Investigator

LEUKAEMIA & LYMPHOMA RESEARCH
Beating Blood Cancers

OPTIMAL

MAIN INCLUSION CRITERIA

- Male or female, aged 18 years or above
- Patients with newly diagnosed symptomatic myeloma
- Glomerular Filtration Rate (GFR) <30 mls/min
- CKD stage 4 (15-29 ml/min) and CKD stage 5 (<15 ml/min)
  Where there is a pre-existing medical condition which may cause renal damage, there must have been a further decline (≥15 mls/min GFR) between previous steady state and the study screening
- Women of childbearing potential (WCBP) and male patients whose partner is a WCP must be prepared to use contraception and comply with the Thalidomide Celgene™ Pregnancy Prevention Programme
- Free of prior malignancies for ≥ 2 years *with exception of currently treated basal cell, squamous cell carcinoma of the skin, localised prostate cancer or carcinoma "in-situ" of the cervix or breast*

MAIN EXCLUSION CRITERIA

- Female participant who is pregnant, lactating or planning pregnancy during the course of the trial or the female partner of a male participant planning a pregnancy during the course of the trial
- Known allergy to investigational drugs
- Any of the following laboratory abnormalities: Absolute neutrophil count (ANC) < 1.0 $x10^9$/L; Platelet count <75 x 10^9/L; Serum SGOT/AST or SGPT/ALT >3 x upper limit of normal
- Use of any standard/experimental anti-myeloma drug therapy excluding dexamethasone 14 days prior to trial entry
- Intention to use a physical method of serum free light chain removal such as plasma exchange or high cut off dialysis
- Grade 2 neuropathy or more
- Participants who have participated in another research trial involving an IMP in the past 12 weeks
- Contraindicated to receive either one of the study drugs, thalidomide, Bortezomib, Bendamustine

STAFF AT OPTIMAL TRIAL OFFICE

For all other trial enquires please contact the Trial Coordinator on 01865 223 353 or **optimal.trial@nhs.net**

Chief Investigator: Dr Karthik Ramasamy **kramasamy@nhs.net**
Sponsor: Oxford University Hospitals Trust
Funders: Janssen Cilag & NAPP Pharmaceuticals Ltd.

NEWSLETTER

Oxford University Hospitals NHS
NHS Trust