

# HAEMATOLOGY & TRANSPLANT RESEARCH TEAM

DECEMBER 09 ISSUE 2

## WELCOME!

Welcome to the second edition of the Haematology and Transplant research team newsletter!

Every 3 months we will keep you fully informed of the team's activities. In addition to this, in each issue we will be looking at specific studies which are new or are facing recruitment difficulties....

## STUDY STATUS UPDATES...OPEN

### INSIDE THIS ISSUE

OPEN TRIALS	P1
OPENING SOON	P2
FOCUS ON..... CLL Admire	P2
FOCUS ON ..... CLL RIBECCA	P3
GCP & CONTACT DETAILS	P4

### AML / MDS

- **AML16:** NCRN study for older AML/high risk MDS.
- **AML17:** NCRN study for adults with AML/high risk MDS
- **AML Len 5 :** Lenalidomide as monotherapy & in combination with standard chemotherapy for AML/high risk MDS with chromosome 5 abnormalities.
- **Romiplostim:** A randomized study of Romiplostim for thrombocytopenia in low or INT-1 Risk MDS.
- **MDS Registry Study:** European registry for newly diagnosed MDS with low or INT-1 Risk.
- **AZD1152 C14 Mass Balance:** Phase I study assessing metabolism, excretion & PK of AZD1152 and AZD1152 hQPA following IV administration of [<sup>14</sup>C]-AZD1152 in AML.

### MYELOMA

- **Myeloma X:** NCRN study to determine the role of a 2nd autologous transplant following prior high-dose chemotherapy and autologous transplant.
- **Velcade:** Randomized study of subcutaneous and intravenous VELCADE in previously treated myeloma.
- **Vantage:** Open-label study of Vorinostat in combination with Bortezomib in relapsed and refractory multiple myeloma.
- **Myeloma IX:** Myelomatosis therapy trial for patients of all age groups. Relapsed sub protocol.

### ALL

- **UKALL2003:** UK national randomised trial for children and young adults with ALL.

### CML

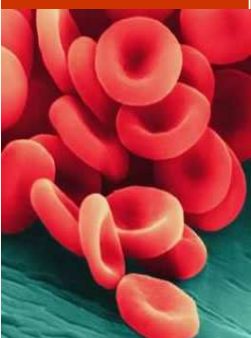
- **Spirit 2:** Randomised comparison of imatinib and dasatinib in newly-diagnosed chronic phase CML.

### TRANSPLANT

- **Ricza:** Adjunctive azacitidine in patients undergoing RIC allogeneic transplantation for AML or MDS.

### CLL

- **The Continuum Trial:** Lenalidomide as maintenance therapy for B-cell CLL following second-line therapy.

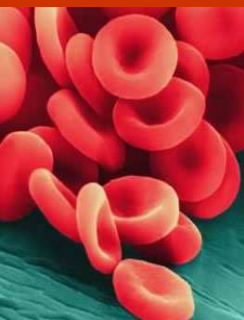


## STUDIES IN PLANNING

FOCUS  
ON...

Every issue we will be focusing on a specific study or disease area in order to increase recruitment. Please see our focus on CLL pages this month featuring two studies which will be suitable for your CLL patients. See pages 2 and 3 for more details.

We will be closely monitoring outside referrals to studies and presenting a league table so make sure you're top of the league for recruitment!



- **Admire:** NCRN comparative study of FCR vs FCR plus mitoxantrone in previously untreated CLL.
- **ReACH:** A study of reduced intensity sibling allogeneic transplantation for relapsed, chemosensitive, PET positive Hodgkin lymphoma.
- **PAIReD:** Reduced intensity transplantation using the BEAM-Alemtuzumab protocol for primary refractory/relapsed refractory Hodgkin's disease.
- **RiBECCA:** A Phase IIIb study of Rituximab with bendamustine or chlorambucil in patients with CLL.
- **CMML201:** A phase II study of azacitidine in CML.
- **CLL009:** A study of the safety and efficacy of different Lenalidomide dose regimens in subjects with relapsed or refractory B-Cell CLL.

## FOCUS ON... CLL

## ADMIRE

**A randomised phase II trial of fludarabine, cyclophosphamide and rituximab (FCR) with or without mitoxantrone (M) in previously untreated chronic lymphocytic leukaemia.**

**Study Objectives:** Does the addition of mitoxantrone improve response to FCR chemotherapy in patients with CLL

**Inclusion criteria:**

- Male or female; age > 18 years
- B-CLL with a characteristic immunophenotype
- Binet's Stages B, C or progressive stage A
- No prior therapy for CLL
- At least one of the following: progressive marrow failure, massive, progressive or symptomatic splenomegaly or lymphadenopathy, or progressive lymphocytosis
- At least one of the following: unintentional weight loss within the previous 6 months, significant fatigue, fevers for 2 or more weeks, night sweats for more than 1 month

**Exclusion criteria:**

- Active infection
- Past history of anaphylaxis following exposure to rat or mouse derived CDR-grafted humanised monoclonal antibodies
- CNS involvement with CLL
- Mantle cell lymphoma or an active secondary malignancy (excluding basal cell carcinoma)
- Symptomatic cardiac failure, HIV, active or prior hepatitis B or C

**Treatment schedule**

Patients will be randomised to receive either FCR or FCR-M, cycles of both regimen's will be repeated every 28 days for a total of 6 cycles.

**WE NEED  
YOUR  
HELP!**

As a tertiary referral centre we specialise in clinical trials that may not be available anywhere else in your catchment area. We ask you to review all your CLL patients who may be eligible for our CLL studies. We are relying on outside referrals to recruit to these studies, so please get in touch.

If you would like any more information about any of our studies, contact details for the research team are available on page 4.



## FOCUS ON... CLL

### RIBECCA

**A Randomized phase IIIb study of Rituximab added to a chemotherapy, Bendamustine or Chlorambucil, in patients with Chronic Lymphocytic Leukaemia.**

**Primary Objective:** To compare the confirmed complete response rate after 6 cycles of treatment between two treatment arms for **first and second line treatment of CLL in patients ineligible for fludarabine.**

**Inclusion Criteria:**

- Age > 18 years
- Tumour cell phenotype consistent with CLL: CD5+ CD20+ CD23+
- Active CLL with progressive Binet stage B or C
- Ineligible for treatment with fludarabine
- For second-line patients only pre-treatment with Rituximab and/or Chlorambucil is allowed

**Exclusion criteria:**

- Patients who have received prior treatment with Rituximab or Chlorambucil who have relapsed in less than 12 months since the first dose of first-line therapy
- Previous or planned autologous or allogeneic stem cell transplant
- Radioimmunotherapy within the last 6 months
- Previous treatment with Ofatumumab
- Patients with transformation to aggressive B-cell malignancy
- Known or suspected CNS involvement
- Malignancy within the last 2 years except for cervical carcinoma (stage 1B or less), non-invasive basal or squamous cell skin cancer, malignant melanoma with a CR duration > 10 years, other cancer diagnosis with a CR duration of > 5 years
- Chronic or ongoing infectious disease requiring treatment
- History of cerebrovascular disease, HIV, hepatitis B or C infection
- Life expectancy of less than 6 months
- Known or suspected hypersensitivity to components of the investigational product
- Medical condition requiring the use of oral corticosteroids

**Treatment schedule**

The study will be conducted in two patient sub-populations with CLL, first-line and second-line patients.

Study medication will be given for up to 6 treatment cycles in the Rituximab plus Bendamustine group and up to 12 treatment cycles in the Rituximab plus Chlorambucil group. In the Chlorambucil group if the patient has not received CR, the patient may be treated with Chlorambucil monotherapy until either CR is achieved or an additional 6 cycles have been completed.

Each cycle is 28 days in duration.

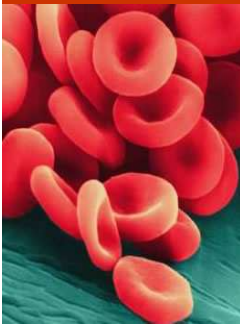
## DATES TO KEEP IN MIND!

**NEXT  
ISSUE**  
March 10

Focus on...  
transplant studies.

Remember to look out for our first study referral league table, so start looking out for patients !!

**ADDRESS**  
Haematology and Transplant Unit,  
The Christie NHS Foundation Trust,  
Wilmslow Road,  
Manchester,  
M20 4BX.



### IS YOUR GCP TRAINING UP TO DATE?

If you are working in clinical trials, it is essential that you complete GCP training and update it every 2 years.

The following dates for Christie GCP training are available:

**Thursday 03 December 2009**

**Wednesday 31st March 2010**

Update sessions are being held on:

**Tuesday 30th March 2010 (am or pm session)**

To book on please contact Kate Carr-Deed in R&D (Kate.Carr-Deed@christie.nhs.uk), if these dates are not suitable and your training is due please contact Antonia Veale for alternative external courses (Antonia.Veale@christie.nhs.uk).

## CONTACT DETAILS

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## STAFF NEWS

We would like to welcome Research Nurse, Nita Smeeton, to the team. She joins us from the Rheumatology Research Team at Leeds Teaching Hospital NHS Trust.

